Volume 7

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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

BEFORE THE HONORABLE EDWARD M. CHEN

FOOD & WATER WATCH, INC., et al, Plaintiffs, vs. U.S. ENVIRONMENTAL PROTECTION AGENCY, et al, Defendants.	)	No. C 17-2162 EMC San Francisco, California Wednesday June 17 8:30 a.m.

TRANSCRIPT OF REMOTE ZOOM BENCH TRIAL PROCEEDINGS

APPEARANCES:

For Plaintiffs:

WATERS KRAUS & PAUL
222 North Pacific Coast Highway
Suite 1900
El Segundo, California 90245
BY: MICHAEL P. CONNETT, ESQ.
CHARLES ANDREW WATERS, ESQ.

WATERS & KRAUS LLP
3141 Hood Street
Suite 700
Dallas, Texas 75219
By: KAY GUNDERSON REEVES, ESQ.

(APPEARANCES CONTINUED ON FOLLOWING PAGE)

Reported By: ***Debra L. Pas, CSR 11916, RPR, RMR, CRR***
Official Reporter - US District Court
Computerized Transcription By Eclipse

APPEARANCES: (CONTINUED)

For Plaintiffs:

NIDEL AND NACE, PLLC
5335 Wisconsin Avenue, NW
Suite 440
Washington, DC 20015
BY: CHRISTOPHER THOMAS NIDEL, ESQ.

For Defendants:

U.S. DEPARTMENT OF JUSTICE
Environmental Defense Section
601 D Street, NW
Room 8814
Washington, DC 20004
BY: DEBRA J. CARFORA, ESQ.

U.S. DEPARTMENT OF JUSTICE
Environment & Natural Resources Div.
P.O. Box 7611
Washington, DC 20044
BY: BRANDON N. ADKINS. ESQ.
SIMI BHAT, ESQ.
JOHN THOMAS H. DO, ESQ.

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P R O C E E D I N G S

JUNE 17, 2020 8:30 a.m.

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THE CLERK: Court is now in session. The Honorable M. Chen is presiding.

Calling Civil Action 17-2162, Food & Water Watch versus Environmental Protection Agency.

Counsel, please state your appearances for the record, beginning with plaintiff's counsel.

MR. WATERS: Andy Waters for the plaintiff.

THE COURT: Good morning, Mr. Waters.

MR. WATERS: Good morning Judge.

MR. CONNETT: Good morning, Your Honor. Michael Connett for the plaintiffs.

THE COURT: All right. Good morning, Mr. Connett.

MR. NIDEL: Good morning, Your Honor. Chris Nidel for the plaintiffs.

THE COURT: Thank you, Mr. Nidel.

MS. CARFORA: Good morning, Your Honor. Debra Carfora for EPA.

THE COURT: All right. Good morning, Ms. Carfora.

MR. ADKINS: Good morning, Your Honor. Brandon Adkins for EPA.

THE COURT: All right. Thank you, Mr. Adkins.

MS. BHAT: Good morning, Your Honor. Simi Bhat for

EPA.

THE COURT: Good morning, Ms. Bhat.

MR. DO: John Do for EPA. Good morning, your Honor.

THE COURT: All right. Good morning, Mr. Do.

THE CLERK: Your Honor, I am promoting Kay Reeves into the well.

THE COURT: Okay.

THE CLERK: Ms. Reeves, please state your appearance for the record.

MS. REEVES: Yes. I don't quite have my video. Good morning, I'm here for the plaintiffs, your Honor.

THE COURT: All right. Good morning, Ms. Reeves.

Okay. What has the plaintiff decided with respect to rebuttal?

MR. CONNETT: Your Honor, we have one rebuttal witness, Dr. Kathleen Thiessen.

We also have one document that was not pre-admitted. There is no objections to the document that we seek to admit at this time, which is Plaintiff's Exhibit 32.

THE COURT: All right. No objection?

MS. BHAT: One second, your Honor. Let me see what that is.

(Brief pause.)

MS. BHAT: Your Honor, I'm not sure if this exhibit was ever discussed in testimony.

MR. CONNETT: Your Honor, during Dr. Thayer's testimony on Friday, there was a discussion about the use of animal data in risk assessment where there is an applicable human study that allows for a BMDL.

This mercury document show that the agency does consider animal data, including reference dose derivations from animal data to increase the confidence in the risk determination.

THE COURT: Well, but it wasn't -- it wasn't brought up during examination or cross; correct?

MR. CONNETT: Well, Dr. Thayer did specifically discuss the mercury assessment. And so we think that this document provides context for understanding how EPA has used animal data to increase the confidence in the risk characterization.

THE COURT: All right. Is there an objection?

MS. BHAT: Your Honor, we're just not sure that it's necessary to have this as an exhibit if it was never actually discussed.

I mean, the appropriate time to have brought this up would have been during the cross-examination of Dr. Thayer.

MR. CONNETT: There is no objection, your Honor, to this document. So there is no -- there was no relevance objection to this document.

The way we have been proceeding with the litigation, you know, with the pre-admission of documents, I think it's

consistent with how we have approached exhibits in this case.

THE COURT: All right. So just to be clear, there is or is not a formal objection to this?

MS. BHAT: Your Honor, it is an EPA document. It is authentic, we agree.

It's just that it doesn't -- without any context of questioning Dr. Thayer about this document, we're not sure how it's useful to the Court's decision-making.

THE COURT: All right. I'm going to admit it. However, I don't think it has much probative value, frankly. It would have been more valuable to have some question and answer about it. But as it just sits there as a document, I guess you can make whatever points you want to make.

I'll admit it, but I'll indicate that its probative value is probably minimal.

MR. CONNETT: Thank you, Your Honor.

(Trial Exhibit 32 received in evidence)

THE COURT: All right. Do you want to call Dr. Thiessen then?

MR. CONNETT: Yes, Your Honor.

THE COURT: Okay.

THE CLERK: Dr. Thiessen is being promoted into the virtual well.

THE COURT: Okay.

(Brief pause.)

THE COURT: Good morning, Dr. Thiessen.

THE WITNESS: Good morning, your Honor.

THE COURT: All right, Mr. Connett. Go ahead.

KATHLEEN THIESSEN,

called as a witness for the Plaintiff herein, having been previously sworn, resumed the stand and testified further as follows:

DIRECT EXAMINATION

BY MR. CONNETT

Q. Dr. Thiessen, on Monday Dr. Chang stated that hypersensitivity to fluoride has not been documented in double-blinded studies; is that correct?

A. That is false --

MS. BHAT: Objection, Your Honor. Scope.

THE COURT: Overruled.

MS. BHAT: Objection. Your Honor, let me please explain.

I don't believe that Dr. Thiessen has ever discussed the studies that Mr. Connett is referring to in her disclosures.

MR. CONNETT: Your Honor, these studies were discussed at length during Dr. Thiessen's direct examination. They are cited in her expert report, and they are cited in her expert declaration.

If there was a scope objection, it should have been raised during her direct exam.

THE COURT: All right. Overruled.

MS. BHAT: Your Honor, I did raise a scope objection during the direct exam and what I was told is that these studies were discussed in NRC 2006, which the witness did cite to in her expert report.

However, it has come to light that the NRC document that Mr. Connett was referring to was actually NRC 2009, and that document was not discussed by this witness in this context.

THE COURT: All right. What about that?

MR. CONNETT: Well, first off, counsel has misrepresented to this Court the NRC 2006 document in their brief last week.

The NRC report cites Dr. George Waldbott's 1978 book, where Dr. Waldbott summarizes the case reports that he published in the 1950's and 1960's.

Counsel took that -- Dr. Thiessen's statement, that there were case reports from the 1950's, looked at the NRC report and didn't find a specific reference in the neurotoxicity section to the 1950's case reports, but failed to disclose to your Honor that the neurotoxicity section specifically cites to Dr. Waldbott's 1978 book, which is a summary of all of his case reports.

So I would ask that -- I think counsel is making a long objection. I think it's taking up my time, and I would -- I believe this objection is completely without merit.

THE COURT: All right. Objection overruled. The defense has enough familiarity. You can -- you're not prejudiced. You can examine on cross.

Go ahead.

BY MR. CONNETT

Q. Dr. Thiessen, was Dr. Chang correct that there have not been double-blinded studies showing hypersensitivity to fluoride?

A. That is false.

Q. Have headaches been reported as a symptom of fluoride exposure in double-blinded studies?

A. Yes.

Q. Dr. Chang mentioned a 1971 position paper by the American Academy of Allergy. Was the NRC aware of this position paper when it issued its reports on fluoride in 2006 and 2009?

A. Yes.

Q. Did the NRC find that the studies on fluoride hypersensitivity to be credible?

A. Yes.

MS. BHAT: Objection, your Honor. Can we be specific about which NRC document we are discussing?

THE COURT: Please clarify.

BY MR. CONNETT

Q. Did the NRC in both its 2006 and 2009 reports find the studies on fluoride hypersensitivity to be credible?

A. Yes.

Q. Dr. Tsuji testified on Monday that she was not sure whether adults can ingest a dose of .02 milligrams per kilogram per day from drinking fluoridated water.

Dr. Thiessen, can adults exceed --

MS. BHAT: Objection. Misstates testimony.

MR. CONNETT: Your Honor, let me --

THE COURT: You can ask -- hold on. Hold on.

Ask the question without -- you don't need to reference -- incorporate into your question every single -- you've done this a lot. Did you testify X, Y? Just ask the question.

MR. CONNETT: Understood, Your Honor. Thank you.

BY MR. CONNETT

Q. Dr. Thiessen, can adults exceed .02 milligrams per kilogram per day of fluoride from drinking fluoridated water?

A. Yes.

Q. Now, you're familiar with the Mullenix study; correct?

A. Yes.

Q. Were there any body weight changes or signs of systemic toxicity in the prenatally exposed animals in the Mullenix study?

A. No.

MR. CONNETT: That's all the questions we have, your Honor.

THE COURT: All right. Cross.

MS. BHAT: Thank you, your Honor.

CROSS-EXAMINATION

BY MS. BHAT

Q. Dr. Thiessen, in NRC 2006 the NRC stated that there was not robust evidence of any hypersensitivity to fluoride; correct?

A. I believe it's not robust, but there is evidence.

Q. In fact, and it's a not robust statement that was referring specifically to the gastrointestinal hypersensitivity; correct?

A. Those studies are discussed both with respect to gastrointestinal sensitivity and neurological things.

Q. But in the context of hypersensitivity, that was the reference to gastrointestinal hypersensitivity; correct?

A. I don't remember exactly.

MS. BHAT: Mr. Hambrick, can we pull up Exhibit 13, Page 318.

Permission to refresh. Excuse me, your Honor.

THE COURT: Go ahead.

MS. BHAT: Exhibit 13, Page 318.

(Document displayed.)

MS. BHAT: Mr. Hambrick, can you go to Page 297 -- I'm sorry, Mr. Hambrick. You were on the right page. I just missed it. Okay.

Can you blow up the bottom half, the "Findings" part of

the page?

(Document enlarged))

BY MS. BHAT

Q. Dr. Thiessen, this discussion of robust data, that relates specifically to gastrointestinal effects; correct?

A. This particular discussion, yes.

MS. BHAT: Thank you, Mr. Hambrick. You may close the screen.

(Document removed from display)

BY MS. BHAT

Q. Now, Dr. Thiessen, in NRC 2009 the -- is it true that the NRC in 2009 concluded that the -- concluded that there were experimental studies on anti-thyroid effects referencing Galletti, Galletti and Joyet; is that true?

A. Yes.

Q. And isn't it true that in Galletti there was actually a beneficial association between fluoride exposure and potential hypothyroidism; correct?

MR. CONNETT: Vague and ambiguous.

THE COURT: Overruled.

A. My memory is that the Galletti and Joyet study looked at use of effectiveness of fluoride in treating hyperthyroidism by reducing the thyroid activity in hyperthyroid individuals. Beyond that, I don't remember any details right now.

Q. And that study described it as a beneficial effect;

correct?

A. In treating hyperthyroidism that could be considered a beneficial effect, yes.

Q. Now, Dr. Thiessen, isn't it true that even a well-conducted study can yield false positives?

A. That happens sometimes, yes.

Q. And isn't it true that even a well-conducted study can yield false negatives?

A. It happens sometimes, yes.

Q. You cannot evaluate consistency on a basis of one data point; correct?

A. Consistency, by definition, requires more than one data point.

Q. The EPA guidelines that you cite rely -- require that you consider consistency across studies; correct?

A. I believe that's in there, yes.

Q. The EPA guidelines on which you rely also require you to consider non-positive data; correct?

A. Yes.

Q. The EPA guidelines on which you rely also require you to consider significant data gaps; correct?

MR. CONNETT: Your Honor, at this point we're beyond the scope of rebuttal.

THE COURT: Sustained.

BY MS. BHAT

Q. Dr. Thiessen, you were discussing the Mullenix study. That was just one study; correct?

A. One study, yes.

Q. And you reviewed over 100 animal studies; correct?

A. Yes.

Q. And no other studies that you reviewed found gender specific effects indicating sensitivity in male rats; correct?

A. That is probably not correct.

Q. No other animal study that you reviewed indicated that males had a more sensitive effect than female offspring; correct?

MR. CONNETT: Your Honor, at this point we're beyond the scope.

THE COURT: Well, I'm going to allow this question to be finished.

A. There were other studies that reported gender differences. I don't have the details in front of me right now.

BY MS. BHAT

Q. The other study that reported -- the only other study that reported gender differences was Bartos 2019; correct?

A. That one did report gender differences.

Q. That was the only other study; correct?

A. I -- that I don't know at the moment.

Q. You do not know.

Bartos 2019 showed more adverse effect in female offspring than in male offspring; correct?

A. Yes. But the Mullenix study and the Bartos study were designed differently, and so there could -- could reasonably be differences expected.

Q. Now, when you're assessing the Mullenix study, are you applying a weight of the evidence approach?

MR. CONNETT: Your Honor, this is beyond the scope. It was a simple question about the Mullenix study. It was just about whether there were body weight changes. That's it.

THE COURT: Overruled.

A. Could you repeat the question, please.

BY MS. BHAT

Q. When you are evaluating the Mullenix study, are you applying a weight of the evidence approach?

A. Yes.

Q. Now, weight of the evidence approach requires that you consider significant data gaps; correct?

A. When one is looking at a big picture. When one is looking at one study, the criteria have to be different.

Q. Well, you cannot be looking at just one study and be using a weight of the evidence approach; correct?

MR. CONNETT: Your Honor, at this point it is -- this is beyond the scope.

THE COURT: Sustained.

MS. BHAT: Your Honor, I have no further questions at this time.

THE COURT: All right. Anything on redirect?

MR. CONNETT: No, Your Honor.

THE COURT: All right. Thank you.

(Witness excused.)

THE COURT: Any further witnesses?

MR. CONNETT: Not from plaintiffs, your Honor.

THE COURT: All right. Then both sides rest?

MR. CONNETT: Yes. For plaintiffs.

THE COURT: And EPA?

MS. BHAT: Excuse me. Can we please confer? There was some suggestion that we might be reading from those deposition transcripts, and I just wanted to doublecheck with my colleagues.

THE COURT: All right.

MS. BHAT: Actually, they can just hop on and let me know.

MS. CARFORA: Your Honor, EPA rests.

THE COURT: All right. Both sides rest.

Let's see. Angie, what, does the clock show?

THE CLERK: Okay, your Honor. Plaintiffs have 30 minutes and 36 seconds remaining.

Defendants have 30 minutes and 11 seconds remaining.

THE COURT: All right. What I'm going to do is give

each side 40 minutes, because I may ask questions and I'm going to count that on my time and not yours. So I don't want you to speed talk. You know, it's important enough, so I want to give you 40 minutes. And if I end up asking a lot more questions, I may give you more, but I want you to assume 40 minutes.

MR. CONNETT: Thank you, Your Honor.

THE COURT: So are you prepared to start now or would you like a 10-minute break?

MR. CONNETT: If the Court would indulge us, a 10-minute break would be great, but we're prepared to start now as well.

THE COURT: Well, I'll tell you what. I'll give you a 10-minute break because I want you to be organized, and we'll have enough time to complete this morning.

And after conclusion of your closings, I do want to discuss with you sort of where we go from here, because I have some questions generally about that, but we'll get there. But my main goal is to complete today, and we will be able to do that.

So we will take a 10-minute break.

MR. CONNETT: Thank you, Your Honor.

THE COURT: Thank you.

THE CLERK: Court is in recess.

(Whereupon there was a recess in the proceedings from 8:48 a.m. until 9:00 a.m.)

THE CLERK: We will resume. Court is back in session. Please come to order.

THE COURT: All right, counsel. We've to the closing arguments, and the plaintiffs can proceed.

CLOSING ARGUMENT

MR. CONNETT: Thank you, Your Honor.

May it please the Court. On behalf of the plaintiffs I wish to begin today by expressing our immense gratitude for having had an opportunity to present our case in court, and in so doing to give voice to those who have too often been voiceless, and to hold accountable an agency that, at least on this particular issue, has failed to responsibly carry out its duties to protect this nation from harm.

In most cases closings are about argument, but today, Your Honor, I'm not going to argue that much. Because the undisputed facts in this case speak for themselves.

So I begin, Your Honor, by addressing a simple yet fundamental question to this case. What is a risk? What is the standard that EPA uses to determine when a risk exists?

First off, we know that TSCA commands that the EPA protect not just the general public, but susceptible subpopulations as well, including pregnant mothers and bottle-fed infants.

The statute makes clear that if there is one unreasonable risk to one susceptible subpopulation, EPA must take regulatory action to protect from harm.

So what is a risk? As Dr. Thiessen explained to Your Honor, a risk exists if the human exposure level is unacceptably close to the estimated hazard level. EPA has not and does not require data demonstrating that human exposures under the condition of use cause the hazard.

Now, Your Honor, this standard is not in dispute. Indeed, it is an undisputed fact in this case, undisputed fact No. 16, that EPA does not require that human exposure levels exceed a known adverse effect level to make a finding of risk.

But despite this, Dr. Tala Henry admitted yesterday in no uncertain terms that EPA has from day one of this litigation used the wrong standard. They used the wrong standard of risk to assess the plaintiff's evidence.

Now, each and every one -- as Dr. Tala Henry talked about yesterday, each and every one of EPA's experts in this case used a causation standard to assess the evidence, not a risk standard.

Now, causation is relevant, your Honor, to a risk finding, but it is not and never has been a pre-requisite to a finding of risk.

So now I'll talk about the experts that your Honor has heard from in this case. The three experts that EPA called to the stand to discuss fluoride were not actually experts on fluoride prior to this litigation. But as you heard, Your Honor, EPA does have experts on fluoride at the agency,

including Dr. Kristina Thayer.

Now, EPA did call Dr. Thayer as a fact witness to discuss the process of systematic review, but EPA avoided asking Dr. Thayer the obvious. They avoided asking Dr. Thayer for her assessment of the fluoride literature.

It was the plaintiff's, Your Honor, not the EPA, who asked this question. And Dr. Thayer agreed that fluoride damages the brain and that the animal data supports the biological plausibility of fluoride causing neurotoxic effects in animals.

So why did EPA go outside the agency and higher experts from Exponent? I submit, Your Honor that the answer to this question is obvious and needs no further comment from me.

Although plaintiffs are citizen groups and without the resources of the EPA, we brought before your Honor world-class experts of the highest caliber. Experts who have devoted their professional lives to understanding the impact of environmental chemicals on human health. Experts who EPA has consistently relied upon for protecting this nation from harm. This includes Dr. Howard Hu. This includes Dr. Bruce Lanphear. And Phillipe Grandjean. And Dr. Kathleen Thiessen.

And as you heard, Your Honor, there is no substitute for expert judgment. No matter now many thousands of pages a systematic review may be, at the end of the day the determination of risk will always come down to expert judgment.

And as you have heard throughout this trial, EPA's own

actions show that the agency trusts the expert judgment of plaintiff's experts.

EPA has based its regulations on the major neurotoxicants, lead and mercury, on the research of plaintiff's experts. EPA has awarded plaintiff's experts tens of millions of dollars in research funding.

EPA contracted with Dr. Thiessen to write the agency's health assessment on fluorides.

And EPA has repeatedly invited plaintiff's experts to serve on its science advisory boards, including as recently as two weeks ago.

By contrast, Your Honor, the record in this case is devoid of any evidence showing EPA has ever once relied on the expert judgment of the Exponent scientists it retained. Not a single solitary example.

So I'll talk now about the methods, the methods that plaintiff's experts used to assess the evidence in this case.

The TSCA statute commands that EPA base its decisions on the best available science, and we brought that science before your Honor. Dr. Hu and Dr. Lanphear explained how their NIH funded cohort studies easily satisfied EPA's definition of best available science. This is not even in dispute.

Dr. Chang has admitted that these studies are the best, most rigorous studies ever done on fluoride and neurodevelopment.

The methodology used by Drs. Hu and Lanphear underwent extensive vetting. Before they even did the studies, they underwent extensive vetting by the NIH specialist committees. And then after they did the studies and got the results, you heard testimony that they submitted these -- these studies to world-class leading scientific journalists, who then did another round of extensive peer review.

And as you heard, Your Honor, the -- on the MIREC and ELEMENT studies had extensive control for potential confounders. And unlike the much cruder studies from New Zealand, the NIH studies had individual measurements of fluoride during the critical window of development, the prenatal period, just as recommended by the Faroes statement back in 2007.

In addition, the examinations were fully blinded, eliminating the potential for examiner bias, and the studies investigated so-called optimal levels of fluoride exposure that are added to drinking water here in the United States.

So in addition to providing the best available science, Dr. Grandjean conducted an extensive weight of the evidence analysis in which he focused and he gave greatest weight to the best available science. And as Dr. Thayer explained on Friday, this is the approach that EPA has used since its inception to assess the risk of environmental chemicals, a weight of the evidence analysis that focuses on the best available science.

Additionally, both Dr. Grandjean and Dr. Thiessen conducted the functional equivalent of a systematic review. For Dr. Grandjean, he built upon the systematic review that he had published in 2012. In addition, he fully considered the systematic review conducted by Dr. Chang in this case.

And as Dr. Thayer explained on Friday, it is not a recommended practice that even EPA agrees with that when you are doing a systematic review, you can and should build upon existing systematic reviews.

Dr. Thiessen, meanwhile, conducted a risk assessment under the Guidelines for Neurotoxicity Risk Assessment, which Dr. Henry explained yesterday is the effective equivalent of a systematic review.

So, Your Honor, you've heard this concept at points throughout this case of fit for purpose. This is a concept that EPA specifically discusses in the risk evaluation rule. It's a concept that recognizes that a risk evaluation under TSCA is not a straightjacket. EPA recognizes that there is room for practicality. There is room for flexibility. There is room for common sense.

This recognition is embodied in this concept of fit for purpose. And both Dr. Grandjean and Dr. Thiessen conducted fit for purpose assessments in this case, and there has been no demonstration to the contrary.

So now, Your Honor, I will turn to the evidence.

At the beginning of this case I said that there were three key questions that need to be answered:

Is there a hazard? Is there a risk? And is the risk unreasonable?

The undisputed evidence in this case, we submit, demonstrates that the answer to all three of these questions is yes.

First, it is undisputed that fluoride passes through the placenta and gets into the fetal brain. This means that when a pregnant mother drinks a glass of fluoridated water, the fluoride in the water will have access to the child, including the brain.

It is also undisputed that, unlike older children and healthy adults, a young child does not have the protection of the blood-brain barrier in utero and in early infancy. In fact, as you can see in this undisputed fact in the case, the blood-brain barrier is not fully developed until six months after birth. And because of this, Dr. Thayer explained on Wednesday that the EPA recognizes we need to pay special attention to chemical exposures that occur during the first six months of life.

Yet, Your Honor, that is precisely what happens when we add fluoridation chemicals to drinking water. It is undisputed, undisputed that babies who are bottle fed with fluoridated water receive the highest doses by far of any age

group in the population. At the moment of their greatest vulnerability, we are exposing infants, often from the poorest and most disadvantaged communities, to a very high burden of fluoride.

Now, there is no dispute in this case, Your Honor, that fluoride damages the brain. The NRC made this finding as far back as 2006. And the CDC representative in this case, Casey Hannan, who you heard from, testified that the CDC agrees with with the NRC's summary of the hazard, including the NRC's summary of the neurotoxic hazard.

And here you can see, Your Honor, the finding of the NRC, that:

> "It is apparent that fluorides have the ability to interfere with the functions of the brain."

Now, at that point, Your Honor, they were focusing on the neurochemical and neuroanatomical effects because there was not many learning and memory studies then available, but many such studies have since become available.

Now, while EPA's experts in this case have criticized the methods of many of the studies, it is important to keep in mind what they do not dispute. No one came before your Honor to say that fluoride is not a neurotoxicant. So the question of hazard really is not in dispute in this case.

Here you can see testimony from Dr. Joyce Tsuji. I asked her:

"**QUESTION:** You do not dispute that neurotoxicity is a hazard of fluoride exposure; correct?"

And her answer was:

"**ANSWER:** Yes, at high enough levels."

But what EPA didn't do is they never even attempted, never once attempted to determine, but what are those levels? They never attempted to provide to Your Honor an estimate as to what the levels are that are causing these neurotoxic effects.

The record is devoid of any EPA expert in this case making any attempt to do that. But importantly, they do not dispute that fluoride will damage the brain at a certain dose.

THE COURT: And my understanding is that they didn't do so because the levels that -- that all of these studies that you're talking about show involve levels well above the exposure levels of humans in the United States. I think that's the EPA's position; right?

MR. CONNETT: Well, that -- the problem with that position, Your Honor, is even -- Dr. Joyce Tsuji testified on Monday that she accepts that 20 parts per million in the water of rats is effectively the equivalent of 1.3 parts per million in the water of humans.

And, your Honor, it's a well-accepted principle in --

MS. BHAT: Objection, your Honor. That misstates testimony.

THE COURT: That's all right. I have the evidence.

I'm not going to take objections over mischaracterizations of evidence. You can argue in your counter argument.

MR. CONNETT: And Your Honor, it's a -- as Dr. Thiessen explains in her declaration, it's absolutely standard practice for EPA, when interpreting animal data, to do an analysis of -- for calculating the human equivalent dose.

And so for fluoride specifically we know that rats need more fluoride in their water to obtain the same level of fluoride in their blood. That's a toxicokinetic difference.

THE COURT: I understand that, but 1.3 is still well above -- isn't that well above the exposure levels in the United States?

MR. CONNETT: Not at all, your Honor. And that is only -- just to put this in context. That 1.3 figure, Your Honor, that's just -- that's just providing you where you've -- you've done an analysis for interspecies differences. You still need to -- under EPA risk assessment you still need to provide a factor to assess, to account for human-to-human differences.

So going from 20 to 1.3, Your Honor, all that is doing is its getting you -- it's adjusting for interspecies differences. Interspecies differences.

Then you also need to do an adjustment for human-to-human differences. And as we've talked about throughout this case, EPA almost always uses an adjustment of 10. So if you put the

adjustment of 10 to that 1.3 figure, you're down to .13.

So it's -- it's important when looking at animal data, that you -- we can't treat the water fluoride level in rats as equivalent to the water fluoride levels in humans. They are very -- you need to dose the animals at substantially higher levels.

And, also, you need to account for the fact that you have much fewer rats, much fewer animals. You know, with fluoridated water you have 200 million people drinking it.

So the EPA, Your Honor, it is standard practice for the EPA to -- to make adjustments to the animal data to account for the differences in susceptibility between rodents and humans.

And so in terms of this hazard assessment, Your Honor, we have, as you've heard throughout this case, four high quality prospective cohort studies. Each of them have found significant associations between early life fluoride exposures and large reductions in IQ on the magnitude of up to five points, when you go from zero to one million gram per liter of fluoride in the urine. That's a very large effect size that rivals the effect of lead.

And under EPA's Guidelines for Neurotoxicity Risk Assessment, the -- the NIH studies are actually sufficient, Your Honor, by themselves. And, clearly, we have a lot of other data biased the NIH studies, but the EPA's guidelines recognize that sufficient evidence of a neurotoxic hazard can

be demonstrated by cohort studies which associate the chemical with a neurotoxic effect. And we certainly have that here in the fluoride database.

And you heard from EPA staff scientist Dr. Joyce Donohue from the Office of Water. She confirmed the obvious, that these are well-conducted studies, but she also said that these studies warrant a reassessment of all existing fluoride standards.

And, you know, Dr. Donohue has focused her work at EPA on the dental and skeletal effects. So the neurotoxicity subject is a bit beyond what she has focused on, but she recognizes that these are high quality studies that warrant a reassessment of the current framework for regulating fluoride.

So that brings us to the second question, Your Honor, is the risk question. Do fluoridation chemicals in water present a risk of this hazard?

And to answer this, I think we again should look for guidance from EPA's Guidelines for Neurotoxicity Risk Assessment. And these guidelines specifically state that:

> "Prospective cohort studies allow the direct estimate of risks attributed a particular exposure."

Again:

> "Allows the direct estimate of risks attributed to a particular exposure."

So we have the proper studies, Your Honor, to make a

finding of risk according to EPA's own guidelines. And this would be, I think, Page 17, Your Honor, of the guidelines, which are in evidence as Plaintiff's Exhibit 17.

And Dr. Grandjean, as you've heard, he did a BMD analysis to take those prospective cohort studies and to assess the risk from those studies.

And this figure, which was discussed during Dr. Grandjean's testimony, shows that pregnant women living in fluoridated areas of both the United States and Canada substantially exceed -- if you just look at the mean levels, Your Honor, the average levels, these average levels substantially exceed the BMDL for a one point loss of IQ.

And when you start to consider the upper range of exposures, which TSCA commands that we do -- TSCA commands that we don't just look at the average. TSCA commands that we look at highly exposed people. If you look at the highly exposed people in fluoridated areas, you are going to see a very large differential there.

And we don't just -- even though the human data, there is no dispute in this case, Your Honor, that the human data is the appropriate data to derive the point of departure. To derive the reference dose. To derive your risk calculations. But that does not mean that the animal data is irrelevant.

EPA has recognized that it -- even where you have high quality human studies, it's still relevant to consider the

animal data, to derive references doses from the animal data because if it's consistent with what the human data shows, it adds robustness and confidence to the conclusions.

And as Dr. Thiessen explains, Your Honor, the animal data, when you calculate the full range of RfDs that can be justified from the data, human exposures from fluoridated water exceed the entire range. Even the least protective reference dose.

Dr. Thiessen, as one of her points of departure, used the McPherson study. And when you use the McPherson study as the point of departure and apply standard EPA adjustments, you get a reference dose that is well exceeded by the exposures to fluoridated water.

So the animal data and the human data are consistent in indicating and showing a risk.

And that brings us lastly, Your Honor, to the question of whether this risk is unreasonable. And as I noted at the beginning of this case --

THE COURT: Before you get to that, let me ask you about the McPherson study, because a lot was made by the EPA that the negative findings of the McPherson study post the -- you know, the systematic review.

Why shouldn't -- why isn't that significant? That is -- you would agree, just as they would agree, that the best studies are the MIREC and the ELEMENT studies on the human side.

Wouldn't you agree that the McPherson study is the best available evidence on the animal side?

MR. CONNETT: I think it is a -- it is a well-done study. It has significant limitations.

But I think, Your Honor, a key point here is this. They -- they max their dose at 20 parts per million.

And I asked Dr. Tsuji: Shouldn't they have dosed the animals at 40 parts per million or 45 parts per million?

And Dr. Tsuji said it wasn't necessary because we know you see effects up in that range.

And so the -- I think that's an important context to put it in. It had a lower dose. And there is no dispute that if you go beyond -- in this case there is no dispute. If you start going down 20 parts per million, you're seeing effects.

So McPherson doesn't do anything to contradict that. And, also --

THE COURT: I thought McPherson found at the maximum they tested, which was 20 parts per million, there were no associations except for pain sensitivity.

MR. CONNETT: Yes, Your Honor. At 20 parts per million in the McPherson study there was an increase in pain sensitivity, which is a neurotoxic effect. So 20 ppm would be a LOAEL for pain sensitivity.

They also found that the rats swam faster. And while it's not dispositive of hyperactivity, it's certainly not a clean

result. It's not a -- this is not a clean bill of health study. You have increase in pain sensitivity. You have rats swimming faster. So it's not a clean bill of health from the McPherson study.

THE COURT: Well, but no -- no association with respect to the critical endpoints of learning and memory. Isn't that significant? I mean, you can't just ignore that.

I know it's not a clean bill of health, but you're looking at an indicator that may not have much association or effect with respect to learning and memory, which is the key here.

MR. CONNETT: Well, a few things, Your Honor, about this.

First is, the McPherson study, as with all animal studies to date, did not expose the neonates to fluoride. Okay? So there is not a single animal study, as we sit here today, that has ever attempted to assess the neurological effects of a critical window of development.

In humans we have -- we have many -- we have many infants who are drinking fluoridated water from day one all the way through infancy. That is a critical window of development. EPA recognizes that. But we have no animal data to assess the neurological effects of that, including McPherson.

Secondly, the McPherson study did not have any exposure during the first six days of gestation. Your Honor, that's about one-third of the gestational period.

And the OECD guidelines say, if you can expose the rats from day zero, do it if you can. They are not saying don't. They are saying if you don't have pre-implantation loss at day zero, dose them at day zero. But McPherson did not do that.

THE COURT: But exposure at day six is also an accepted protocol; is it not?

MR. CONNETT: It is an accepted protocol, Your Honor. It's not as sensitive a protocol as you could have.

So what's important here, Your Honor, is that the study is ultimately not reflecting the full range of susceptibility.

So you can't take from McPherson, you can't have any confident conclusion that the study is capturing what we see in humans, which is full pregnancy exposure, full infancy exposures. It's not there in McPherson.

And, Your Honor in Dr. Thiessen's risk calculations, she treated the 45 part per million concentration, which Dr. Tsuji accepts is a neurotoxic level. She treated that concentration as a lowest observed adverse effect level.

And even if you treat 45 parts per million as a lowest observed adverse effect level, your reference dose is still well below human exposures.

THE COURT: When you apply the uncertainty factors, et cetera, et cetera?

MR. CONNETT: Correct.

THE COURT: But you would agree that you start with

the NTP -- was it the NTP study that gave only low level of -- I forget the term, confidence about effect with respect to infant animals, young animals? And then you add to that McPherson, at least when you look at it on that basis, it appears to me that the animal studies are not very helpful.

MR. CONNETT: Your Honor, I think what's -- as Dr. Thayer testified last week, she said: It's a reasonable hypothesis if the -- if you're seeing learning impairments in the adult treated rats, it's a reasonable hypothesis that you would also see the learning impairments in the developmental studies.

So we can take from the moderate confidence finding that the NTP had in the adult studies, you can impute from that into the developmental studies that if you had the well-conducted studies, you're going to find an effect as well.

THE COURT: Well, that's what I found sort of curious. Why did they have different confidence levels? I mean, based on the -- their review of the literature, you have kind of an inverse relationship.

MR. CONNETT: Right. And I think the reason that Dr. Thayer has provided is that at the time that the NTP did its review in 2016, there were very few developmental studies available. Certainly, few at the -- in the dose range of greatest interest.

So in part, Your Honor, that was why the NTP had lower

confidence in the developmental studies, as well as the issue of not controlling for litter effects, which is, as you have noted, a methodological limitation.

But I don't think we can or should divorce the moderate confidence in the adult studies from our assessment of the developmental studies. It makes no biological sense that you would find learning impairments in adult animals, but not find it in the developmental studies.

THE COURT: So the low level of confidence is due to the nature of the number of studies and the quality of studies and the limitations, not necessarily reflective of the real world.

MR. CONNETT: I believe so, Your Honor. I believe that's what the evidence suggests.

Again, Dr. Thayer said on Wednesday that it's a reasonable hypothesis that if the -- if you're seeing the effects in the adults, you're going to see it in the fetal and neonatal exposures.

And there is no dispute in this case that the developing brain is the most susceptible to environmental toxicants. It would be the *a priori* expectation that an animal exposed in early life will suffer greater effects than animals exposed during adulthood.

THE COURT: Okay.

MR. CONNETT: So now to this question of unreasonable

risk.

And I believe the evidence, Your Honor, in this case -- and you've heard from Dr. Hu, you've heard from Dr. Lanphear and Dr. Grandjean -- is that the situation with fluoridated water today is analogous to the situation this nation once faced with leaded gasoline. There, as here, we have a widespread dispersal of a neurotoxicant, which results in exposure to an enormous amount of people, including the most vulnerable.

It's an undisputed fact in this case that approximately 200 million people live in communities where fluoridation chemicals are added to water, and many more drink processed beverages that have been contaminated with fluoridation chemicals.

To put this number in context, Your Honor, the EPA has found unreasonable risks under Section 6 where the conditions of use impact less than 2,000 people.

Because of the widespread reach of fluoridation, you have millions of susceptible people being exposed on a daily basis, including 2 million pregnant mothers, over 400,000 exclusively formula-fed babies.

Your Honor, these are children -- and most of them are in lower income, more disadvantaged communities. Children who from day one of their life, their only sustenance is infant formula, and that infant formula is reconstituted with the tap

water. These are children who are being placed at a much higher risk of harm, and their interests should be considered by the EPA.

Now, as we have -- you know, plaintiffs do not need to prove causation at .7 parts per million to prevail in this case. That's not the standard that EPA has ever used, as Dr. Tala Henry admitted yesterday. But what makes this case so compelling, Your Honor, is that the evidence actually supports this conclusion.

Dr. Grandjean explained this in his testimony. The Bradford Hill factors support a finding of causation, rather than detract from it.

And we have had -- you know, all risk assessments, Your Honor, have uncertainties. Every single one. I don't think there is a single risk assessment in the history of this world where you don't have some uncertainties.

There are not the exception. They are the rule. Uncertainties do not preclude a finding of risk. If they did, I don't think the EPA would have made many risk determinations with the chemicals it has assessed so far under Section 6.

Exponent scientists that have been in this litigation have identified for Your Honor a long list of possible reasons to possibly explain the findings.

But I think Your Honor's exchange with Dr. Ellen Chang yesterday was notable and important. Dr. Chang was unable to

identify for this Court any reason why the MIREC or ELEMENT studies would have -- why those results would have been biased towards showing an effect.

The EPA, Your Honor, has not identified for you any cogent explanation that can explain the consistent results that we see across the human studies, across multiple populations, multiple study designs, both strong and weak.

Your Honor, we would submit what we submitted at the beginning of this case. The most likely explanation for the consistent results in both animal and human studies is that fluoride is a neurotoxicant that reduces IQ, including at the levels added to community water supplies in the United States. And this effect is strong enough to be detected, even in studies with weak study designs.

So, Your Honor, I believe the preponderance of evidence in this case has demonstrated that fluoridation chemicals present an unreasonable risk of harm.

And we thank you again for giving us an opportunity to present the evidence in this case.

THE COURT: Thank you Mr. Connett.

If I can hear from the government please.

MS. CARFORA: Thank you, Your Honor. I will begin when you're ready.

THE COURT: I'm ready.

CLOSING ARGUMENT

MS. CARFORA: Thank you, Your Honor.

The questions presented to this Court by plaintiffs, both in their opening statement and here again during closing, are overbroad and too simplistic.

I'd like to clarify the actual questions before this Court and explain how the evidence presented fails to provide any of the answers necessary for the Court to find for plaintiffs in this litigation.

But before I do that, I'd like to point out one separate and independent reason why the Court must deny plaintiff's claim.

First, plaintiffs before this Court do not have standing to complain of developmental neurotoxicity. While plaintiffs allege fluoride to be a neurotoxicant, the testimony offered to this Court focused on one specific outcome: IQ deficits or cognitive effects in young children exposed to fluoride in utero and in infancy.

Putting aside the fact that the answer of how much of the mother's internal fluoride exposure can be attributed solely to community water fluoridation, none of these plaintiffs are or were pregnant or alleged future plans for pregnancy. None have infants or even small children. And none of these plaintiffs complain of a concrete reasonable fear of cognitive deficits.

Instead, they complain of self-reported headaches, which

they admit have a long list of other causes.

Now, concerning headaches. Plaintiffs make fleeting references to the following studies.

Roholm from 1939, which discusses occupationally exposed workers at an order of magnitude of 30 milligrams per day.

Two case studies. Waldbott from 1956 and Petraborg from 1974, with no comparison groups, no blinding of doctors, and no evidence of even a statistical association between fluoride at any dose and headaches.

And, finally, a study that plaintiff's own experts call weak, a study out of India documenting self-reported headaches in exposure groups much higher than those relevant to community water fluoridation programs in the United States.

Plaintiffs have not established standing based on the harm presented in their Complaint and the Court must deny plaintiff's claim and find for EPA.

Now, I talked about the second --

THE COURT: Let me ask you -- before you go on to that, let me ask you: I'm hearing sort of two arguments with respect to standing.

One is there isn't sufficient evidence that the complained of symptoms are related or caused by common levels of fluoride exposure. So in other words, they are -- there is no harm, no causal related harm.

Your second argument is that even -- I take it even if

there were, the kind of harm complained of here is not the kind of harm that underpins plaintiff's case, even though they are both neurologically related, if there is such a harm, and both involve the question of neurotoxicity.

Do I understand that correctly?

MS. CARFORA: Yes. In terms of the actual harm complained of, a constitutional standing requires a showing of harm that's -- that's not speculative.

And what we have here, the harm complained of, the only harm which is headaches, self-reported headaches, is speculative based on the information that's in the -- in the record now.

THE COURT: Well, that's the standard. Non-speculative.

I don't have to find as a matter of fact, more likely than not, preponderance of the evidence, that harm actually was causally related. I just have to find it was something above speculation, for standing purposes.

MS. CARFORA: That's right. Yes, Your Honor.

THE COURT: And then the second one. What about -- maybe you can explain your second argument.

If somebody complains of toxicity and they have stomach problems, does that preclude them from pursuing claims that are based on studies that show other health problems? Is there any law or precedent on that point? Remind me.

MS. CARFORA: I'm sorry, Your Honor. That is the zone of interest argument, in terms of what is within the zone of interest between a TSCA petitioner bringing -- bringing their petition before the Court.

Under TSCA a petitioner has the right to have their petition reviewed under Section 21. And here the harms complained of are not supported by the harms alleged in the petition.

And so plaintiffs in this matter do not come within the zone of interest of TSCA to have standing before this Court.

THE COURT: So it is a -- the standing question is a statutory question then, a zone of interest analysis under TSCA?

MS. CARFORA: Yes, Your Honor.

THE COURT: Okay. And remind me, I know we went over this before, but are there cases -- not a lot of TSCA cases, but are there cases that are particularly instructive on this standing question, you know, how one defines zone of interest when it's the same alleged neurotoxin, same alleged idea that it's the neurological aspect of impairment, but different manifestations, different parts of the body?

Is there any guidance there in the case law?

MS. CARFORA: Your Honor, I believe there is. And we did cite to that case law in our summary judgment motion, as Your Honor is aware. And, unfortunately, standing here right

now I am not prepared.

THE COURT: I may ask the parties to take a second look at that and see if there is any new case development in that area.

Go ahead. Thank you.

MS. CARFORA: Thank you.

Your Honor, there are -- moving on to our second point here, there are four questions that are critical to the Court's determination, and plaintiffs have failed to answer any of them.

First question is: Is neurotoxicity a hazard of community water fluoridation?

Second question: What is the internal dose of persons exposed to community water fluoridation programs in the United States?

The third question: Is there any risk posed to persons in the United States from the practice of community water fluoridation programs?

And the last question: If there is a risk, is that risk an unreasonable one?

Turning to the first question: Is neurotoxicity a hazard of water fluoridation? Now, in applying the definition of "hazard" in it's most simplistic form, plaintiffs insist that modern scientific standard and the otherwise rigor required by TSCA should be relaxed because in their view the

neurodevelopmental hazards of fluoride exposure are obvious.

But glossing over the scientific process of evaluating all of the reasonably available scientific evidence in a manner suitable to understand and interpret the existing database for fluoride is plaintiff's most critical error.

In other words, a hazard identification goes beyond merely identifying whether a hazard exists at any level. It requires a full understanding of the strengths, limitations and weaknesses across each individual study and across the database as a whole.

The rigor of the hazard identification process is also critical to carry forward each subsequent component of risk assessment.

Now, as Dr. Hu explained to the Court, quote:

> "When I am serving on committees that are trying to deliberate on policy, we need to look at the whole range of epidemiological studies to understand the impacts, potential impacts, on different populations. And that's also an integral part of the Bradford Hill criteria, which is also cited during this trial as an important tool for looking at all of the evidence and coming to a conclusion."

THE COURT: Let me ask -- hold on.

You framed it one way. The plaintiffs have framed it another way. They are taking it sort of step-by-step. You

start with the broadest question. Is it even possible that fluoride does something to the neurological system in an adverse way? If the answer is no, you don't even get to what level, et cetera. Only then, if the answer is yes, do you then start looking at levels, for instance, to get to the ultimate question.

Your framing kind of gets to the ultimate question, step one. So I don't know -- in the end I don't know what difference it is because you don't even get to your question if there is no hazard to start with, nor do you get to your question if you find that there is not much exposure.

So I -- frankly, I'm not sure that framing this is helpful. What you've posed, number one, is almost the ultimate question. You're one step away. And that's the question whether -- is that an unreasonable risk of hazard.

So I don't want to interfere with your presentation. I know you have a presentation. But I'm letting you know in my mind the critical question to me -- I don't think it's much disputed that fluoride can be a hazard. I don't think anybody disputes that. At some level it's a hazard, a neurological hazard.

The question ultimately is this one: At the community water fluoridation levels at the .7, or around there, and given the way it's used and exposed and consumed by bottle, et cetera, et cetera, does it present an unreasonable risk?

So if you can concentrate your -- I know you're going to get there, but that's the critical question to me.

MS. CARFORA: I understand, Your Honor and I'm hoping to -- I'm hoping to pinpoint that for you over the next couple of minutes.

THE COURT: All right. Go ahead.

Thank you.

MS. CARFORA: Interpretation of the database available for each possible hazard requires professional judgment by a group of experts who understand the application of scientific principles across a number of disciplines.

Let me interrupt myself, Your Honor. I am going to get to your question. I'm just not going to jump there right this second, unless the Court would rather --

THE COURT: No, no.

MS. CARFORA: Thank you.

In this case, plaintiffs criticize EPA for hiring a toxicologist and an epidemiologist whose backgrounds on fluoride are not as robust as plaintiff's own experts.

But you don't have to be an expert in fluoride to speak to the application of toxicological and epidemiological principles. Using that standard, EPA would itself lack the expertise to assess the toxicity of the 80,000 chemical substances currently in commerce.

And let me stop here for a second and just speak to some

of the aspersions cast by plaintiff's counsel in his closing statement.

I'd like to stop and remind everyone that TSCA commands that EPA assess all of the existing 80,000 chemicals in -- currently in commerce. And TSCA creates a pipeline and a prioritization process for EPA to be able to do that.

And what EPA says said in its Guidance to Interested Persons was that we welcome the public's help in trying to assess all of these chemicals, and what we ask from the public is that they present to us draft risk evaluations that meet the same scientific rigor that EPA would conduct under TSCA. And to assist the public in doing that it is issued Guidance to Interested Persons. And not one of plaintiff's experts have cited to that or even acknowledged its existence. And plaintiffs have not -- Mr. Connett has not mentioned Guidance to Interested Persons once.

EPA welcomes the help of the public that meets the scientific rigor necessary to reach public policy decisions.

And I'll move on. And as Dr. Hu pointed out for the Court, subject matter researchers also must avoid the appearance of bias.

More specifically, EPA was careful and deliberate in finding and presenting to this Court an interpretation of the toxicological and epidemiological database for fluoride that has not been tainted by decades of advocacy for or against

community water fluoridation.

For example, plaintiffs stated in their opening that the only risk assessment in this case was produced by Dr. Thiessen. Dr. Thiessen has advocated against water fluoridation since at least 1998. And she has appeared in public meetings and debates on behalf of the Fluoride Action Network and through her advocacy has -- clearly has an interest in the outcome of this litigation.

And, for example, take plaintiff's expert, Dr. Grandjean, who in 2014 wrote that:

> "Fluoride is a known developmental neurotoxicant based on weak evidence."

And who would rather accuse Harvard deans and the World Health Organization of misconduct than accept any scientific criticism of his own work.

And rather than focus on the scientific merit of the systematic reviews completed by Dr. Tsuji and Dr. Chang, plaintiffs accuse them of being hired white coats, who reached conclusions based on the interests of their clients.

But I ask this Court to consider, very simply, what interest does the United States Environmental Protection Agency have in denying the existence of a hazard or a risk?

As plaintiffs pointed out, EPA's mission is to protect the public health. And consistent with that mission, the truth is, if EPA found there was an unreasonable risk from community

water fluoridation, it would take action to eliminate that risk.

Now, more to the Court's point. There are many studies that evaluate associations between fluoride in drinking water and IQ in children. No studies evaluating IQ were conducted in the United States.

And generalizing the results to the U.S. population can be difficult. Many studies were conducted in areas with fluoride drinking water concentrations that are much higher than drinking water fluoride concentrations in the United States. But that difficulty exists for other reasons, too.

As Dr. Hu also reminded this Court:

> "Populations differ for all sorts of reasons. They differ in terms of diet, in terms of genetics, in terms of their social environment, all of which can easily lead to differences in how populations respond to neurotoxicants."

And when focusing on studies with exposures in ranges typically found in the water distribution systems in the United States, studies that could be evaluated for dose response effects, those studies are inconsistent and, therefore, unclear.

Despite there being a number of studies evaluating associations between fluoride in drinking water and IQ in children, including fluoride exposures with concentrations

below 1.5 milligrams per liter, plaintiffs focused solely on the ELEMENT and MIREC cohort studies.

As we explained in the beginning of this trial, the ELEMENT and MIREC cohort studies are among the best conducted human studies to date. But they are relatively recent, and there are inconsistencies within and across those studies.

For example, the ELEMENT study did not find a difference by sex and IQ results, but the MIREC study did. That discrepancy remains unexplained.

The ELEMENT study concluded that there was no clear association between IQ scores and maternal urinary fluoride below .8 milligrams per liter. But no apparent threshold was identified in the MIREC study.

There was no significant association identified between blood plasma and IQ in the ELEMENT cohort, which raises further questions about what the proper measure of fluoride exposure is telling us, urine versus blood.

In both cohorts the relationships observed between IQ and maternal urinary fluoride were weak, albeit significant.

Now, a hazard also includes a dose response analysis. So the hazard assessment includes both the hazard identification and the dose response.

And the dose response assessment characterizes now this dose level where a potential hazard may become apparent. In other words, it answers the question before us now: At what

exposure does a hazard become apparent through a manifestation of effects?

The dose response assessment builds upon the systematic review that was done in the hazard I.D. by documenting the justifications and the limitations for the key study or studies being used to identify a dose response and to extrapolate to a protective reference dose.

Now, as Dr. Thayer explained, the preferred method for calculating a reference dose is the benchmark dose approach. Dr. Thayer explained that this is because the NOAEL/LOAEL approach is constrained to the experimental doses, rather than the shape of the dose response curve.

Now, what Dr. Thiessen did is she derived a range of reference values based on the NOAEL/LOAEL approach as applied to certain animal data, but Dr. Thiessen's approach was critically flawed in three ways.

First, as the Court has already recognized, Dr. Thiessen used unreliable data to extract points of departure. The National Toxicity Program's systematic review found extensive bias in the experimental animal literature. And not just because there were too few of them, but what Dr. Thayer testified to was systematic bias across the studies and indirectness in the results.

And the NTP -- and Dr. Tsuji's update of the NTP review confirmed that the bias continued in the more recent studies

with the exception of NTP's McPherson 2018.

Now, that study, of course, as you've already recognized, did not find effects on learning and memory with increased fluoride exposures at doses that exceed the general population.

And to just expand a little bit on what you were talking about with Mr. Connett. McPherson 2018 found a NOAEL at the 20 milligrams per liter. Now, this 1.3 ppm that plaintiff's counsel was referring to was actually after -- in the testimony it was actually after he had applied a number of factors to that number to get it down to 1.3. But above the 20 milligrams per liter, we actually don't -- we don't know where the effects start to show.

Now, what Dr. Tsuji testified to was above 20 milligrams per liter, we start to see systemic toxicity in the animals; that the animals start losing body weight. And she said she didn't know if that was because they didn't like the taste of the water or, you know, they didn't like the taste of the food. But because there was systemic toxicity in the rats, you couldn't really tell what was going on with -- from exposure to fluoride above that level.

Now, the second --

THE COURT: Can you comment on Mr. Connett's statement that Dr. Thiessen derived her -- I don't remember if it was point of departure or reference dose, based on the McPherson study? Do you take issue with that?

MS. CARFORA: Well, the problem is, Your Honor, as I remember it, what Dr. Thiessen -- Dr. Thiessen did not identify specific studies.

What Dr. Thiessen did was identify, I think it was four LOAELs and two NOAELs. And those LOAELs and NOAELs were derived from, you know, so a narrative review included in her report and her declaration that grouped a handful of studies together.

So she said at .5 -- you know, at 5 milligrams per liter these studies all found a NOAEL or LOAEL.

At 20 milligrams per liter these studies found a NOAEL/LOAEL. She wasn't specific to a study.

Now, what plaintiffs have extracted throughout this trial is that they should focus on McPherson, and rightfully so. The problem is there is no individual interpretation of the McPherson study that Dr. Thiessen did. There is no justification, scientific justification offered. I'm not saying that one might not exist. I'm saying none was offered.

And without having some scientific justification being offered, it's impossible to know whether the McPherson study really is or is not appropriate for that particular purpose.

THE COURT: Well, let me ask you kind of a basic question to make sure I get this.

If a study doesn't show any association effect, at least with respect to memory and learning, the more direct

endpoints -- putting aside pain sensitivity for a second -- that would mean there is no LOAEL; right? It's only a NOAEL. If you only test up to a certain level and you don't see anything, you only get a NOAEL.

MS. CARFORA: That's right.

THE COURT: And you don't know where the LOAEL would begin.

MS. CARFORA: That's correct.

THE COURT: So how does one use such a study to calculate any kind of point of departure?

MS. CARFORA: Well, and this -- this is exactly the point, Your Honor, is that what you do is you have look across all of the studies.

So you have to understand: Is this my key study? Why is this my key study? What are the limitations in this study? And is there anything else in the database that fills those data gaps for me? Is there anything else in the database that I can go back to?

And what's -- the studies that fill those data gaps, what are the qualities of those studies? What are the limitations in those studies? How do I fill those data gaps?

This is exactly the point as to why it's not straightforward. It's exactly the point why systematic review is necessary.

You have to have an understanding of all of the studies in

the database to be able to know if you have data gaps, how to close those gaps, and whether you have the information or not.

But more to the point here, what's so interesting about what you're saying is that NTP's 2016 systematic review identified all these gaps; right? Just what the Court is talking about. It identified all of these gaps.

And you heard Dr. Thayer talking about: NTP said let's design a study that tries to address all of these gaps. Let's design a study the best we can to get towards those low dose levels that we're so interested in and try to correct for the bias and indirectness we're seeing across the database.

And NTP did that. And they did that with people who have expertise in animal neurotoxicity. And they went out and they designed the study the best they could, a suite of studies I think we heard. I think the number might have been nine. And based on that study they found no effects.

And so the question becomes, quite honestly, is this -- this study might be the best study, but is it appropriate for deriving an RfD. And we need to understand the entire database to be able to answer that question.

THE COURT: And so the EPA's position, as I understand it, is that, yes, in order to derive a point of departure, you have to kind of look at all of the studies to determine where some of the LOAELs and NOAELs are, but you give different weight to different studies in making that

determination depending on their degree of reliability?

MS. CARFORA: That's right. You have to understand -- yes.

THE COURT: And that in this case the most reliable standout would be the McPherson study. The other studies, which were rated by the NTP as sort of low confidence.

MS. CARFORA: Well, I think, Your Honor, even that question remains unanswered.

I think the question is, you know, if -- like Dr. Tsuji testified to. It is the best existing study right now.

But the question is: Is it enough? Is it enough to close those data gaps? Is it enough to get it to tell us, you know, if there is a NOAEL, what is the level where we actually start to see exposures?

You know --

THE COURT: Let me ask you, the ratings of the NTP, as I recall, there were four classification from, like, very low or -- the very bottom, I think it was very low or something, then low, and then moderate, and then high or something like that.

MS. CARFORA: I think that's right, Your Honor.

THE COURT: All right. So with respect to the infant studies, it wasn't the very bottom. It was low, but it wasn't worthless. I mean, those studies had some value. It just was low. It was, like, the third out of four categories; right?

MS. CARFORA: It's another great point you're making, Your Honor, because I think that what NTP said, and what EPA would say, is all you need is one study to get above that very low threshold. One well-designed study, I think is what we would say -- what EPA would say, and NTP, to get above that low threshold.

So if you're going to say -- and remember, Dr. Thayer explained for us. If you're going to say that there is no evidence whatsoever, you know, you would have to -- you would have to be able to prove that there is nothing out there that shows a potential risk.

THE COURT: Where would I find the criteria that the NTP uses? Is it in the report where they define what those are?

MS. CARFORA: Yes, Your Honor, it is. And it's in evidence.

And I can't believe I -- I hope I get this right. I can't believe -- I might know. It's EPA's Trial Exhibit 518, which is the -- no. Which is the OHAT handbook. OHAT is the NTP program. And in that handbook for systematic review I do believe that they talk about the different levels of -- levels of evidence.

And I would expect that it is true that also in EPA Exhibit 553, which is the NTP 2016 report itself, I'm sure that they also describe the levels of evidence in there.

THE COURT: And what about the dialogue I had with Mr. Connett about that it seems counterintuitive that you would find an effect in adult rats, but not in infant rats, given the developmental stage, the window and all that.

Is that explained simply by the quality of the research and availability of the research and not that it is likely there are effects on adults, but none in infants?

And, in fact, the -- it's a compound question, but the fact that there is a higher level, moderate level of confidence with respect to the effect on adult rats, wouldn't that imply that if you have the same quality of studies, you would have -- you would find effect on infant rats?

I mean, how many could it be -- how could it not be?

MS. CARFORA: If I could clarify the Court's question, just so I'm -- I make sure I understand what you're asking.

THE COURT: I think -- what I'm asking is: The fact that the NTP 2016 study showed -- found a moderate level of, I guess, confidence, whatever it is, in the adult rat studies, animal studies, from that shouldn't one infer that there is likely an impact on infant rats?

And the only reason why the NTP rated it as low level of confidence was there just wasn't very many good studies out there. Not that it doesn't exist. The phenomenon doesn't exist. It's just the quality of studies weren't very good.

MS. CARFORA: Well, let me take a step back. There's a couple things.

I think it's factually inaccurate to say that the reason why NTP found a low level of evidence in animals exposed during development was just because there was a low number of studies. I don't believe that to be factually correct.

I mean, I think Kris Thayer said the problem was in that -- in the developmental studies specific was indirectness. They couldn't -- they didn't know whether, you know, changes in the animal's motor and sensory functions were causing the delay in cognitive effects. And they -- it was too indirect, and they couldn't make that cause there.

But, you know, I think that --

THE COURT: Well, also, many were hampered by the -- not taking into account the litter effect; right? That affected a number of those studies.

MS. CARFORA: Well, yes. And that was a bias; right? That was a different --

THE COURT: Right.

MS. CARFORA: -- a different reason. That was the bias, the systematic bias across all the studies that showed the lack of blinding.

But there was also the second factor, which was indirectness.

So I mean, I think the question is: Can't we assume, you

know, that if -- if there is moderate level at -- for adults, that there would be a moderate level for infants.

And I think quite honestly, Your Honor, the answer is if we could assume that, then NTP would have assumed that, but they didn't. They very specifically made the distinction, and they were careful about that.

And I'm not -- you know, I'm not a toxicologist, but I think -- you know, if I could just take this question and take this discussion kind of to the next level. Because I think the bigger issue is, you know, I -- I don't think anyone could dispute that there is a hazard at some level. But the question now becomes for everyone, is that level anywhere relevant to community water fluoridations and exposure in the United States?

And this is where we start -- this is where we're in, the second piece of this hazard assessment, which is the dose response. And this is -- and this is what we used the systematic review for so specifically here, which is now we need to be able to see, is there any indication that the dose is any -- you know, the hazardous dose is anywhere near what's being exposed. And we have to look at these studies.

And what Your Honor -- you know, I think Your Honor is correctly focused on McPherson, but I think even McPherson still leaves questions.

And more to the point, nobody has got in -- what

Dr. Thiessen offered was a scientifically or methodologically inferior process to the BMD process; right?

So I think what would happen is you would have some experts, people who have expertise in rat neurotoxicity and toxicodynamics, and all of those torts of things. They would go into McPherson and try to fit the McPherson, you know, study with their BMD models, and they might do that.

Or they might decide, through systematic review, that the human evidence is more relevant, because what we have heard testimony on is if there is an abundance of human evidence, the human evidence is more relevant. And you can rely on the animal database where you need to try to close some of those gaps, but given the human database that we have for fluoride, it's more relevant and I think methodologically more appropriate to look at the human studies, and look -- look -- start there in terms of trying to find --

THE COURT: I agree. But why don't we focus on the human studies, if you could.

MS. CARFORA: Sure. And I'll -- if it's okay with Your Honor, I would like to keep going through. I'm definitely going to get there.

THE COURT: Okay.

MS. CARFORA: If you would bear with me.

THE COURT: Okay.

MS. CARFORA: So Dr. Grandjean also derived a range

of reference values using a BMD analysis applied to Bashash 2018 and Green 2019.

But Dr. Grandjean's testimony vacillated between being able to conduct a BMD calculation on the back of an envelope, to having to rely on a world expert on benchmark dose to do the calculation for him.

But nevertheless, the most telling -- the most telling thing about the level of confidence one could have in the offered BMD was Dr. Grandjean's testimony that once he can gain access to the raw data from both the ELEMENT and MIREC study, he can, quote, calculate the real benchmark dose.

But even more fatal than that is the inability for anyone to critically assess or replicate the calculations due to the glaring lack of transparency in both his declaration and live testimony. And these critical flaws carry forward through the remainder of Dr. Grandjean's analysis and further discredits the reliability of his ultimate conclusions.

And I'm going to go into those studies now.

The next question then before the Court is: What is -- we need to understand what is the internal dose of persons exposed to community water fluoridation programs in the United States?

Plaintiffs submit that maternal urinary fluoride is the proper metric for measuring fetal exposure. And the Court heard a lot of testimony comparing neurotoxic effects of lead exposure to the potential neurotoxic effects of fluoride

exposure.

But to compare the well and long-established impact of lead on IQ, and studies that have quantified the blood lead IQ relationships over multiple populations, to the more limited evidence base for fluoride is just simply not justified.

The relationship between --

THE COURT: Can I back up just for a second here, going back to Dr. Grandjean and lack of transparency.

MS. CARFORA: Yes.

THE COURT: My recollection is that he had to digitize from the scatter points, right, all points of data?

MS. CARFORA: For one study that was published at the time he conducted his report.

THE COURT: Right, right. Did the EPA ever attempt to replicate that on its own? Did it have any of its experts try to do that and see whether they came out with different results?

MS. CARFORA: We did not, Your Honor.

THE COURT: Did the EPA have access one way or the another through discovery to those data points, the raw numbers that fit into the BMD calculation? Not the back of the envelope, but the ones he had his colleague perform? Was there any discovery on that?

MS. CARFORA: So there is no raw data available. The Bashash 2017 study clearly was published before -- before

expert discovery started. And so there was access -- there was access to Bashash 2017.

But from EPA's perspective, we never -- EPA never got to the dose response assessment because we never got past the hazard assessment question.

THE COURT: I'm asking -- the question I'm asking in discovery --

MS. CARFORA: I understand, Your Honor.

THE COURT: And --

MS. CARFORA: I understand. I'm sorry.

THE COURT: You had a chance to depose. You had a chance to subpoena or request documents.

Did you ever request that Dr. Grandjean produce the digital results of that scatter plot so you could run it? Without having to digitize it yourself, have your experts run it and see whether his -- his calculations or his associate's calculations were verifiable or not?

MS. CARFORA: We did not. And the Green -- the Green 2017, Your Honor -- I'm sorry, 2019 study, that was not -- that was not published -- it was published toward the end of expert discovery. It was actually published the night before Dr. Henry was deposed. And so we -- we were in the middle of expert discovery at that point.

And Dr. Grandjean, when he -- his second supplemental expert report was based on the manuscript, not the published

version. And so -- so that study wasn't even published while we were still going through expert discovery.

THE COURT: I mean, you have had time. I guess, my point is, if you're making a transparency point, I think the obvious comeback to that is that what he did, his methodology and his source of information were transparent through his declaration. Whether -- and provided ample opportunity for subpoenaing documents and conducting cross-examination, conducting a parallel calculation to impeach his calculation.

So, frankly, I'm not as concerned about transparency in that -- as to that particular issue.

But go on.

MS. CARFORA: Let me respond.

That's what I was getting to. When you say that we should have or maybe we should have requested the information and run the calculations ourselves, I mean, that's what I was trying to get at just a couple minutes ago when I was trying to say EPA never got there. They never get to the dose response because without the systematic review, you know -- quite frankly, if EPA would have run the data or run -- it would have given credibility to using that study in the first place.

And the point is, there is really no credibility for using that study without having the systematic review. Without knowing whether that is the key study, there is no point in doing that exercise --

THE COURT: Well, there is a point in litigation. If you know the other side is going to rely on somebody's study and analysis to derive a critical component of the risk evaluation, you have the opportunity to examine that, without making any concession.

You say, well, we didn't want to make a concession that these studies were reliable, and you don't have to. You just -- all you need to do is say his studies are hogwash or his calculation was wrong. Here is the error. Here is what we came up with. That doesn't admit anything.

In any event, let's move on. I'm not -- let's go on to the next point.

MS. CARFORA: The relationship between blood lead and IQ decrements has been studied for many years and has a very large body of data underlying the blood lead IQ relationship.

For example, there have been numerous cohort studies of population groups from cities across the United States, as well as in other Western countries.

And while the relationship between the urinary fluoride and IQ are recent -- recently described by Bashash 2017 and Green 2019, using small non-U.S. populations at one point in time, the generalizability to even the full Mexican and Canadian populations are unknown, but unquestionably do not approach the generalizability of evidence base for blood lead and IQ relationships in the U.S. population over time.

Now, currently the variability and uncertainty associated with the urine-fluoride IQ relationship is largely unknown due to so few studies being available. And Bashash 2017 and Green 2019 actually highlight the large variability associated with the use of urine as a measure of fluoride exposure.

For example, measures of fluoride in urine is a short-term measurement of exposure that is highly variable due to a number of factors, including the time of sampling, hydration state, and the methods used to correct for hydration.

Additionally, measures of fluoride in urine are also subject to confounding, which is why we need more than these two cohorts to understand the true nature and the uncertainty in using urine as an exposure metric.

And Dr. Lanphear and Dr. Hu highlighted this variability in their testimony.

First, Dr. Lanphear testified that:

> "It's hard to predict water concentrations from urinary fluoride alone and that other sources factor into the concentration observed in urine."

Dr. Hu testified that:

> "Whether the source of fluoride exposure is from salt or water could affect the concentration of fluoride observed in a spot urine sample."

Now, that's important, Your Honor, because we know that Mexico fluoridates their salt, not their water.

Now, given all of the uncertainty and variability, we simply do not know enough about the urine-fluoride IQ relationship to determine whether the MIREC and ELEMENT cohorts provide the best available methodology for estimating the internal dose from exposure to community water fluoridation, and as a result, this question remains unanswered.

I'll move on to the next question, which is: Is there any risk posed to persons in the United States from the practice of community water fluoridation?

Despite the current variability and uncertainty in using maternal urinary fluoride as a reliable exposure metric in the MIREC and ELEMENT populations, Dr. Grandjean doubles down on that uncertainty by comparing his BMDL to maternal urine-fluoride concentrations found in pregnant women in Northern California. This was the UCSF study the Court heard about.

Now, although testifying via declaration that the comparison of maternal urine-fluoride concentrations reported in the UCSF study to the Green study concentrations was, quote, ultimately the most important consideration, Dr. Grandjean testified that he never even compared the final published version, peer-reviewed published version of the study, with the manuscript that he relied on in forming his opinion that the association reported in the US -- and he testified that the association reported in the UCSF study was weak, statistically

non-significant, and not even indicative of true maternal urine-fluoride levels of the California women studied.

Now, hazy BMD lines and weak associations simply do not rise to the level of best available science for the purpose of justifying EPA regulation.

THE COURT: Hold on. Let me ask you some questions right there.

You criticize his reliance on the draft and not the final study. Remind me, the final published version came out with different numbers?

(Brief pause.)

MS. CARFORA: Your Honor, I don't have that information standing here right now.

But the concern is that Dr. Grandjean couldn't tell us that either. So the problem is, he offered an opinion in this case. It was based on a manuscript, an unpublished manuscript that he disclosed to EPA five days before his -- his deposition in this case.

And, no, he never even confirmed -- he offered a declaration based on the published version of that report, even though that was published after expert discovery was closed, and he never -- he couldn't testify that he compared those two studies.

So we don't know, standing here right now, whether there were any differences in the manuscript or the published

version.

THE COURT: Well, that may go to his credibility and what you might call lack of rigor.

But the material question, seems to me, the substantive question is: Did he rely on an erroneous number? Was it corrected in final? Which is something you would have access to and could have crossed him on. It would be useful to know if -- if, in fact, he relied on a number that was materially changed as a result of -- between going from draft to final, and he relied on a number that was outdated, that would be significant.

MS. CARFORA: Well, two points, Your Honor. I did cross examine him on that. I did ask him if he compared it, and he said, no, he didn't compare it.

So there is that point, but I --

THE COURT: But does the EPA have information to show that that final number was different?

MS. CARFORA: I don't have that information standing here right now.

THE COURT: All right. Then let me ask you -- actually, I'm trying to remember now the testimony about the weak correlation.

The correlation was between what? What was the correlation that was weak?

MS. CARFORA: The correlation between maternal

urinary fluoride concentrations and community water. I believe it was -- and the community water measurements that they -- that they were comparing that to.

THE COURT: Community water measurements of their -- I'm trying to remember now, of their home?

MS. CARFORA: It was -- I believe it was -- if I don't have the number wrong, I think it was 51 women who were giving birth in San Francisco. They were not from San Francisco, but they were in San Francisco overnight. San Francisco fluoridates water. So they had drank water in San Francisco and had given a urine sample.

And this study was comparing the urine samples from just those 51 women from all parts of the Bay Area against water community -- community water fluoridation in San Francisco.

So it wasn't even indicative of where these women actually lived. It was indicative of just comparing their maternal urinary fluoride to -- that's not true actually.

They did compare -- they compared their maternal urinary fluoride to the -- the reported community water concentrations of where they lived, where they reported they lived.

THE COURT: Where they lived.

MS. CARFORA: They did.

THE COURT: And some --

MS. CARFORA: They did.

THE COURT: And some came from non-fluoridated areas;

is that right?

MS. CARFORA: Well, I don't think we know that information.

What Dr. Grandjean -- I believe what he testified, though, that it wasn't indicative -- the water fluoride concentrations of those women wasn't indicative of where they lived because they were in San Francisco the night before and had been drinking water in San Francisco, which we know does fluoridate water.

THE COURT: Does the EPA have information to suggest that the median levels found and the distribution of the levels found in these 52 women -- 51 women were not accurate? Were not reflective of other fluoridated communities?

MS. CARFORA: Well, I mean, I think -- I mean, I think it's -- the point is that their urine samples -- as Dr. Lanphear and Dr. Hu testified, your urine sample was going to be indicative of, you know, your most recent intake. So the idea is their most recent intake was in San Francisco.

And so you're comparing, you know, their most recent intake in San Francisco to their community water fluoride concentrations in their homes. And so that's the logical leap in understanding that it's not indicative because urine samples is such a short-term measurement.

THE COURT: Well, short-term measurement, and the most recent exposure was in San Francisco.

It seemed to me the question is whether San Francisco fluoridation -- community fluoridation levels are consistent with what we see throughout the country? Is there anything unique about San Francisco fluoridation level?

MS. CARFORA: Not that I understand, but I do -- I think the -- I think the Court is raising the right question, is -- can we assume -- or should we assume that these 51 women are -- represent the entire United States? And I think quite clearly the answer to that is no.

I mean, I believe there was testimony by Dr. Lanphear and Dr. Hu that even the ELEMENT -- you know, Mexico City itself is not indicative of all of Mexico in terms of intake or maternal urinary fluoride.

And the same in Canada. I mean, the study in Canada, the MIREC cohort is a big cohort, and it covered a number of cities. But I think there was testimony that even -- even those maternal urinary fluoride concentrations are specific to that population, and not to the -- to all of Canada.

Now, can you do that? Maybe. But the question is should you.

And I think, you know, the question of saying should you use one study out of California with 51 women who are about to give birth in a city drinking water that's different than the water that they are intaking at home, should you use that as a way to generalize maternal urinary fluoride concentrations

across the United States. And with --

THE COURT: Did the EPA introduce any evidence to suggest that was not a good representative -- in other words, if there are sort of national standards and you know the distribution from the EPA exposure, that big table, right, from 2019?

MS. CARFORA: Yes.

THE COURT: Is there anything -- when you compare the San Francisco concentrations -- and I don't remember if they are at .07 or what -- whether that puts them outside that range? Where does San Francisco fall in that big national study?

MS. CARFORA: Well, Your Honor, I have an answer for you, but I'm not sure it's in evidence. And so --

THE COURT: Well, that's something -- if it was outside, that would have been useful information because you could have impeached the value of the UCSF study in terms of it's generalization and its reliance and --

MS. CARFORA: Your Honor, I think that --

THE COURT: -- and Dr. Grandjean's reliance on that by showing that he relied on a particular study that was not representative or was outside the mainstream of that -- of the study that the EPA did. I didn't hear that.

MS. CARFORA: Well, first, I think that Grandjean impeached himself by suggesting that it was a weak correlation

and that it wasn't indicative.

In fact, what Dr. Grandjean said when we pointed out it was a weak correlation, what he says is: Well, I just cited to the UCSF study because it seemed important to EPA. What I was using was the World Health Organization's, you know, measurement.

So, you know, I think that -- the study has been impeached and, you know, we -- again, you know, the -- we talked about -- you heard testimony from the CDC about NHANES. And NHANES is the entity in the government that takes all of these measurements, and it takes the measurement across the entire U.S. population.

And there is no evidence in this trial by anyone as to whether those -- and for what years those urinary fluoride concentrations exist; if they exist, for what years; and what those numbers are.

But, surely, the NHANES data would be a much more appropriate and reasonable measurement than 51 pregnant women in San Francisco in terms of generalizing that information to the United States.

THE COURT: The NHANES is the -- is the intake measurement, the amount -- the concentration of fluoride in community water; right?

MS. CARFORA: No. The NHANES actually does go out and test biomeasurements of fluoride -- of a lot of things, but

it does do it for fluoride as well.

THE COURT: Urinary measurements?

MS. CARFORA: So there's some dispute about whether NHANES actually has reported the data yet. Again, that's why I want to be very, very careful here.

But it is -- urinary fluoride is something that the NHANES could do for the entire country.

THE COURT: But what the -- the table we saw was with fluoridation levels of community water, wasn't it? Did I get that wrong?

MS. CARFORA: That's right. No, that was EPA's Exposure Factors handbook, which was a systematic review of the available evidence on intake, on water intake across different subpopulations and at different percentiles.

Now that intake, that exposure, is different from dose. So the -- you know, the intake is the exposure and the urinary fluoride is the internal dose.

THE COURT: Okay. All right. Go ahead.

MS. CARFORA: We did hear a lot of testimony from Dr. Grandjean that on his chart he included a hazy BMD line. And I submit that a hazy BMD line and weak associations do not rise to the level of best available science for the purposes of justifying EPA regulation.

Now, the final question before the Court is: If there is a risk, is the risk an unreasonable one?

And plaintiffs argue that the purported risk of community water fluoridation is unreasonable, in part, on the potential extent and magnitude of exposure to fluoridation chemicals. And it is true that these are factors EPA has said it would consider in finding -- in making a finding of unreasonable risk.

But before EPA or the Court ever gets to these considerations, plaintiffs must first set forth a scientifically defensible basis to conclude that any persons are at risk of neurotoxic harm as a result of exposure to community water fluoridation.

In this forum that means that plaintiffs need to show that it's more likely than not that fluoride causes neurodevelopmental harm at a dose experienced from exposure to community water fluoridation programs.

The fact that a purported risk relates to a large population is not a basis to relax otherwise applicable scientific standards in evaluating the evidence of that purported risk.

Now, I want to back up for a moment and verify that, yes, in fact, I said plaintiffs need to show that it's more likely than not that fluoride causes neurodevelopmental harm. And I have no wish nor the skill to embark upon a philosophical discussion on the meaning of causation.

The cause of an illness may be imminent and direct, or it

may be remote and indirect underlying the observed association. But the aim of hazard assessment is to understand the factors of the association before deciding that the most likely interpretation of the association is causation.

THE COURT: Where does this --

MS. CARFORA: Causation --

THE COURT: What is the source of the more likely than not causation? Where does that come from?

MS. CARFORA: More likely than not is the preponderance of the evidence standard.

THE COURT: And where does that come from? What regulation? What statute?

MS. CARFORA: The preponderance of the evidence is the standard under Section 21, for the Court's review, of whether there is unreasonable risk.

THE COURT: All right. And what about causation? Where does causation -- what's the statutory or regulatory basis on that?

MS. CARFORA: Well, as I was explaining, causation is a factor in considering -- I mean, causation is considered as part of the risk assessment process. Meaning, if you have an association, the whole point of risk assessment and looking at these associations is to determine what's your confidence in the association so that the most likely -- the more likely -- the more likely interpretation of that is actual cause. So

this -- this reflects the confidence in the database itself.

I mean, what I'm getting at is causation itself is not a standard. Causation is not a standard. It's not a standard here. But causation is a consideration that has to be part of any unreasonable risk determination, either by EPA or the Court.

So in other words --

THE COURT: There's two ways causation, I understand, comes into this.

One is whether there is a biological or mechanistic plausibility. Because if there isn't, it -- and you -- you know, you would give less weight to it. But if there is, that sort of maybe conforms or corroborates a statistical association.

Number two, causation is statistically -- I would think is something where the association is so strong and the confounders are so confidently eliminated that you can't come to any other conclusion that there is a causal relationship. It is a degree. It is a -- it is at one end of the spectrum of association.

MS. CARFORA: Yes, yes.

THE COURT: So I understand that, but if -- the standard is a lower standard under TSCA. It's association, not causation. I understand if you prove causation, then -- then *a fortiori* you've shown association, but not vice-versa.

MS. CARFORA: I don't think I hundred percent agree with you, Your Honor. It's exactly the point I'm trying to make, is that it's a matter of degree.

But nowhere does TSCA -- the only standard provided in TSCA is unreasonable risk. TSCA doesn't talk about causation or association. It talks about unreasonable risk. And then it says how you go about finding unreasonable risk is you do a risk evaluation. And it defines a risk evaluation, and it defines a risk evaluation of all of the steps of risk assessment, plus a risk determination.

And what I'm suggesting is that causation, the Bradford Hill factors, those are considerations in the risk assessment process.

So there is, you're correct, no statutory place in TSCA that requires causation. And there is no statutory place that talks about association either.

What's required under TSCA to make a finding of unreasonable risk is a risk evaluation. It's a risk assessment that's included as part of that process, and as part of the risk assessment process is a consideration of causation.

You heard Dr. Thayer testify that the Bradford Hill criterias are built into systematic review. They are -- systematic review is the functional application of the words the Bradford Hill criteria say. That's what Dr. Thayer describes, systematic review.

And so there can be no real true dispute that causation as a factor is part of risk assessment, risk evaluation and -- and important to finding -- making a finding of unreasonable risk under TSCA.

THE COURT: Here is the bottom line question. Under Section 21 of TSCA, can the Court find an unreasonable risk without finding causation?

MS. CARFORA: Yes.

THE COURT: But causation is a factor. But it is possible to find an unreasonable risk even without causation?

MS. CARFORA: Yes. And I -- I'll tell you, the risk evaluation process is about interpreting the confidence in the association. It's about determining the degree of causation. That's what risk evaluation is about.

THE COURT: Well, confidence of association and one end of confidence, the very strong end would be causation. Once you've got there, you -- you've pretty much eliminated, at least in the analysis, confounding problems, imprecision problems, enough to find causation.

I mean, to me, association is a spectrum. There's very weak association, no association, moderate, very strong association. And the more and more that statistical strength is, the closer you get to causation.

Is that construct wrong? That spectrum concept?

MS. CARFORA: I think that's right. But I think

that -- I mean, I think we're defining -- we're defining causation in some concrete terms here. And I think in the process of risk evaluation, in the process of risk assessment, the Court was right to say that causation is a matter of degree; that at the end of the day, you know, you have the risk assessment process, but then you have this separate risk determination step.

And in that risk determination step there has to be consideration of is the likely interpretation of this observed association I'm seeing, is that -- does the likely interpretation of that reach some level of causation?

And if you can't say that you -- you can't likely -- you can't interpret the association anywhere near causation, then you have a lot of uncertainty and you can't find a finding of unreasonable risk. You can't regulate on something you don't think is a true association, on something that you don't think is really causing the observed association.

And in that sense it's not a concrete term. It is a level of degree. And we think it's absolutely relevant to the risk evaluation process.

THE COURT: And have there been prior -- I think we talked about this or you all talked about this in the trial. Have there been prior EPA risk evaluations that found an unreasonable risk, but not necessarily causation?

MS. CARFORA: Your Honor, there are no -- let me back

up.

There is one published risk evaluation under the amended TSCA. There are no others.

Now, I believe -- I believe it is correct to say that the one published risk determination under amended TSCA is for 1-BP. And that 1-BP -- the basis of the agency's unreasonable risk finding was based on methodologies applied before the statute was amended.

So on pre-amendments, EPA conducted a risk assessment for 1-BP. When the statute was amended, there was a provision in the statute that allowed EPA to grandfather in whatever risk assessments it had ongoing at the time.

And so 1-BP -- the risk assessment for 1-BP was finished, and the risk assessment was published. And since that time, this statute -- since that time EPA has not yet published one final risk determination.

THE COURT: Okay. The 1-BP, did it find causation expressly?

MS. CARFORA: I'm sorry. That -- it's methylmercury -- no, methylene chloride, not 1-BP. So that was the one that was issued. So I apologize for that.

THE COURT: Okay.

MS. CARFORA: And there is -- there is A 6A rule. So I imagine, I have to assume that they did find unreasonable risk, but I do not know if it was based on causation. And

we'll try to get that information for the Court right now.

THE COURT: And prior to that, prior to TSCA -- or TSCA amendment, were EPA risk evaluations, were there any that found unreasonable risk without causation -- an express finding of causation?

MS. CARFORA: So, Your Honor, let me back up and answer your previous question.

So for -- for the MC determination that we were just talking about, it did -- EPA found that it caused acute toxicity. It caused death. So it did -- EPA did make a finding that it caused death for that determination.

Prior to -- you know the difference between -- one of the big differences between amended TSCA and post amendments was that there was no risk evaluation requirement in the post amendments. And so that process is very different, and that --

THE COURT: Pre-amendment. You mean pre-amendment.

MS. CARFORA: Thank you. Yes, thank you.

The pre-amendments did not have a risk evaluation requirement. And so in the pre-amendments, I believe, it's accurate to say that TSCA relied -- the TSCA program relied on just the existing agency guidance at the time to conduct risk assessments under the policies and procedures available and current in the agency.

THE COURT: And did those existing agency guidance require causation in order to regulate?

MS. CARFORA: I would say -- I think I can fairly say no.

THE COURT: So your position is -- is it your position that amendments to TSCA effectuated a change in that standard?

MS. CARFORA: I'm not saying -- what I'm suggesting is that causation is very relevant to a risk determination. I'm saying that if you're considering unreasonable risk, the statute is very flexible in terms of what you should be considering. And I'm suggesting that making a finding of unreasonable risk based on a weak association or an association that doesn't rise anywhere near the level of causation would be inappropriate.

I'm not suggesting that a risk determination or that amended TSCA requires causation. I'm not suggesting that.

THE COURT: But you are suggesting it has to reach the level of, quote, anywhere near causation in order to constitute an unreasonable risk.

MS. CARFORA: Well --

THE COURT: I'm just using your words.

MS. CARFORA: Appreciate that. Thank you.

And again, it's -- you know, EPA hasn't -- hasn't completed any risk assessments. It said it's going to be very flexible about how it determines risk.

And so one of these issues is uncertainty and variability

in the data. That's a key issue that EPA has expressly said that it would consider. The more uncertainty and variability you have in the data, you know, the -- the harder it is to have confidence in the association itself.

THE COURT: That I understand. You may not even get to a sufficient association if you have too much uncertainty and variability, but that's irrespective of causation.

MS. CARFORA: Well, I mean, I think that's the question; right? I mean, I'm suggesting that -- that's what I'm suggesting, is there's no hard and fast definition for causation here.

I mean, what I'm suggesting is I think -- I feel as if plaintiffs have conflated this causation conversation. We are -- EPA has produced, and we asked our experts to produce, an evaluation of -- to measure the association, to measure our confidence in the association.

And that -- that process of measuring confidence in the association, we've used the term "causation" to -- you know, to describe that process in measuring confidence.

And I think that the -- the reason why we have done that is because the process of risk assessment is the process of determining, you know, how likely is it that the proper interpretation here is that exposure -- this chemical is causing that effect.

I mean, that is the definition of hazard assessment, is

answering --

THE COURT: Where does that come from? Where does that come from?

MS. CARFORA: Well, if the.

(Brief pause.)

MS. CARFORA: I apologize. I'm trying to think if it's in evidence or not. If you can give me one moment on that.

THE COURT: I'm particularly interested if there is a statute or regulation that says that. I'm not sure what you mean by evidence.

You're saying hazard assessment by definition incorporates -- requires causation.

MS. CARFORA: Yes, Your Honor. I'm going to grab Dr. Henry's trial declaration.

(Brief pause.)

MS. CARFORA: Starting at Paragraph 99 all the way through Paragraph 105 Dr. Henry describes hazard assessment. And I'll start at Paragraph 100:

"Hazard assessment, also called effects assessments in some EPA guidance documents, identifies the type of adverse health or environmental effects or hazards that can be caused by exposure to the chemical substance in question and characterizes the quality and weight of evidence supporting this

identification."

She goes on:

"The principles of" --

THE COURT: Let me stop you right there.

Paragraph 100 says "that can be caused" not "is caused" or "more likely than not caused." She just says "can be caused."

MS. CARFORA: Well, I mean, I -- you know, I -- I maintain that, you know, the risk assessment process is about determining our confidence in the association, and that that is specifically relevant to causation.

And I think, you know, as Dr. Thayer testified to, the Bradford Hill criteria and the criteria for causation are built into the systematic review. They are the functional -- systematic review is the functional application of the Bradford Hill criteria, which is the criteria for causation.

And that's what we're looking at. And that's when -- when NTP defines, you know, low, moderate, or -- or high, it's looking at the level of evidence towards causation.

I mean, that's what systematic review is. It's a level of evidence of how likely it is that the chemical substance you're assessing can cause an effect. And that's what systematic review is. And I maintain that that's what risk assessment is.

And if -- you can go through the risk assessment process. You can go through that whole process; right? You can do it on weak data. But the question at the end of the day is: Is the

data I relied on strong enough to regulate on? That's the question.

So, you know, when we're looking at -- and this is what we get to. This is where we have to separate kind of risk assessment pre-amendment and post amendments where you're looking at the risk determination step, where the risk determination step gives the agency the ability to consider those things now. To consider the uncertainties. To consider all these factors that ultimately lead to that question of causation as a matter of degree.

THE COURT: All right. Go ahead. Why don't you finish up?

MS. CARFORA: The Court heard a lot about the applicable scientific standards and methodologies for supporting evidence-based decision-making in environmental public health.

Dr. Kris Thayer, who has been responsible for leading not one, but two United States government program offices recognized around the globe for advancing state of the science for supporting evidence-based decisions making -- evidence-based decisions in environmental public health, laid out for the Court the most current and relevant methodology for addressing hazard and risk questions.

Systematic review is a methodically detailed process designed to ensure objectivity, transparency, clarity,

reproducibility and utility for risk managers.

Dr. Thayer explained the meticulous process of taking a deep dive into each individual study and teasing out the trends related to a number of different biases, domains, within a group of -- with a group of specialized experts across different scientific disciplines so that they can ensure that they are identifying the best possible study or studies to use in subsequent steps in the risk assessment, including the dose response assessment.

Now, plaintiffs concede, as they must, that they did not present to the Court a systematic review. Or in other words, they admit that the information presented to the Court does not represent the current state of the science to support regulatory decision-making. Instead, they asked the Court to believe that systematic review puts form over substance and slows the protection of human health.

But just important as protecting the human -- protecting the public health is EPA's responsibility to preserve and promote scientific integrity in regulatory decision-making.

In fact, the EPA's ability to pursue its mission, to protect public health in the environment, depends upon the public's ability to trust the science and the scientific process that informs public policy decision.

And just as this Court cannot make the best decision unless it has confidence in the integrity of the science on

which it relies, risk assessment and systematic review are the compasses guiding EPA's health and environmental protection decisions; but more specifically, and more relevant here, TSCA demands that those processes be followed prior to granting EPA authority for regulating chemical substances and commerce.

Now, plaintiffs want to sweep these issues of scientific integrity away. They say the Court can make a decision under Section 21 of TSCA divorced of the considerations required by EPA under Section 6. And putting aside that question as a matter of law, I ask the Court as a matter of practicality to consider that if it does make a finding of unreasonable risk, EPA would be required to regulate. Yes, in some manner, but nonetheless, regulate the American people solely on the basis of what has been presented to this Court.

And as you heard from Dr. Henry, EPA's regulations must be supported through the demonstration of clear and transparent scientific judgment, carried forward through each component of a risk assessment process.

And in the absence of an integrated risk characterization that explains all of the key findings, assumptions, limitations and uncertainties in the database, EPA simply does not have the information necessary to reach an informed policy decision concerning the practice of community water fluoridation in the United States.

And I will close, Your Honor, by noting that in 2015 the

National Toxicity Program began the process of evaluating the evidence that exposure to fluoride is associated with neurodevelopmental or cognitive effects. This review was initiated in part in response to a nomination from the Fluoride Action Network, a plaintiff in this case. And maybe the Fluoride Action Network didn't like NTP's initial findings of a low level of evidence to support neurodevelopmental effects in animals exposed to fluoride during development.

But because before the NTP could undertake similar evaluation of the human evidence necessary to reach just a hazard conclusion, the Fluoride Action Network and other plaintiffs petitioned EPA to ban the practice of water fluoridation, otherwise ignoring all of the other risk assessment components and jumping directly to unreasonable risk. And they did so without Bashash 2017 or McPherson '18 or Green 2019 in tow. Which brings us to the present day, and throughout this Zoom trial with a handful of lawyers and experts arguing and interpreting rapidly advancing science.

In fact, simultaneous with this trial the NTP, in consultation with the National Academy of Sciences, is completing a systematic review, integrating the available animal and human data to reach hazard conclusions in a manner that is consistent with the state of the science for reaching such conclusions.

And Dr. Hu and Dr. Lanphear, they continue their research

to close the data gaps and answer outstanding questions.

But despite all of that, plaintiffs are trying to convince this Court that fluoride's neurotoxicity is so obvious that none of this needs to be done. And in the backdrop of the NTP yet to complete even a hazard conclusion, plaintiffs are asking this Court to conclude that it's more likely than not that the practice of community water fluoridation poses an unreasonable risk of neurotoxic harm.

EPA asks the Court to let the science advance. To first verify urine as a appropriate measure of exposure.

Second, apply the science to specific U.S. populations.

Third, conduct additional analysis to better describe and understand the variability and uncertainty in the database.

And fourth, to reproduce the validity of exposure measurements within different Western populations.

There is simply too much uncertainty and variability in the existing database for the Court to make a finding of unreasonable risk. The Court should deny plaintiff's claim and find for EPA.

THE COURT: Let me ask you --

MS. CARFORA: Thank you, Your Honor.

THE COURT: Let me -- thank you, Ms. Carfora.

Let me ask you. The NTP review, that's -- that's the one where there was the draft monograph that had been circulated?

MS. CARFORA: Yes, Your Honor.

THE COURT: And that is -- had been out for review and comment; is that right?

MS. CARFORA: Yes, Your Honor. The draft was published in late October. It was put out -- let me put it this way. It was not published. It was put out for peer review. It went to a National Academy of Sciences peer-review committee.

The National Academy of Sciences posted and published the draft NTP monograph on its website in preparation for the public meeting. The public meeting happened in mid November, I believe. And the National Academy of Sciences finished their peer review and sent the draft back to NTP with a number of comments. And that -- I believe that was February, that the peer review -- actually, the NAS actually published a peer-review report that described its peer review, and it sent that report back to NTP. And NTP has yet to complete or publish a final -- its final hazard conclusions on fluoride, specifically addressing this issue that's before the Court.

THE COURT: So the National Academy published its peer-reviewed comments in February?

MS. CARFORA: Yes, Your Honor.

THE COURT: And now the last step is awaiting NTP finalization after receiving those reports?

MS. CARFORA: Yes, Your Honor.

THE COURT: And your chart looked like you were

forecasting a fall 2020 completion? Do you have any information?

MS. CARFORA: I have not been -- I have not gotten any information since we have been in the COVID-19. I mean, I did -- I don't know.

THE COURT: Okay.

All right. Since Mr. Connett has the burden, I'm going to give him five minutes of rebuttal, if you want a short rebuttal, if you have anything to add or comments.

MR. CONNETT: Thank you, Your Honor.

REBUTTAL ARGUMENT

MR. CONNETT: First, with respect to hypersensitivity, I would just repeat that the National Research Council in both 2006 and 2009 found that the case reports, which included double-blind studies, were credible and the symptoms reported in these studies included headaches.

I would also note that counsel in their PowerPoint slide cited, I think, four studies, which is certainly not the extent of the studies that the NRC relied upon.

In terms of generalizability, Your Honor, as I think has been sort of endemic to EPA's positions in this case, EPA seems to have a double standard. It says we can't rely on studies from Canada and Mexico and, yet, its own experts rely on studies from New Zealand, Canada. And, apparently, they wanted to rely on a study from Spain. I don't recall any discussion

from EPA as to whether those studies are generalizable to the U.S. population.

With respect to animal data, I would reiterate and emphasize, I think, a very central fact in this case. Dr. Kristina Thayer, who is the single -- the one scientist at EPA with the greatest knowledge base on the neurotoxicity literature, she testified in this case that the animal data supports the biological plausibility of fluoride-causing neurotoxic effects in human beings. That is a critical fact. And it's a critical fact when we are assessing the epidemiological data.

With respect to the McPherson study. Counsel misspoke and said that Dr. Thiessen did not rely on the McPherson study specifically for point of departure. That is false. Dr. Thiessen specifically relied on the McPherson study for one of her points of departure. So counsel misspoke.

THE COURT: Remind me. How do you derive a point of departure where there is no LOAEL?

MR. CONNETT: Well, it's a situation -- well, first off, the EPA uses NOAELs, Your Honor, all the time for it's points of departure for risk assessment. It's a standard point of departure to use.

Here, because the McPherson study did not use the higher doses -- and Dr. Tsuji testified that she didn't think they needed to use the higher doses. Here, as counsel, I think,

correctly stated, you can look to the broader literature, look to the dose response that you see in the broader literature, and say: We're clearly seeing affects above 20 ppm. McPherson didn't find an effect on learning and memory at 20 ppm. It's a reasonable point to use for the assessment.

I would agree --

THE COURT: So it looks at -- you look at broader literature in order to give it -- you can't just look at the one study with no effect.

MR. CONNETT: Yes. For instance, Your Honor, if you only had one animal study on fluoride neurotox -- that was it -- and you didn't find any effect at all, then you're not going to -- you're not going to be doing a risk -- you know, you're not going to be creating a -- using that as a point of departure.

It's only when you have a credible basis that this compound causes neurotoxicity, that you would be using McPherson in this way. Because we clearly have animal data showing neurotoxic effects.

Now, I would also note in terms of the concentration that McPherson used, the rats, remember, Your Honor, only had mild fluorosis. And in this country in fluoridated areas you have about 40 percent of children who have at least mild fluorosis. I think that's an important fact to keep in mind when considering the relevance to the United States population.

With respect to -- counsel made a point about the number of studies on lead and IQ that were available to the EPA in 2008 when EPA issued the lead standard. Counsel put on the screen a reference to 6,000 studies.

But if Your Honor may remember, they asked Dr. Lanphear about that on the stand. And Dr. Lanphear made a very important point. He said: Yes, there was a ton of studies on lead.

But at that time there were only three epidemiological studies on lead and IQ at concentrations below 10 micrograms per deciliter. So at the concentrations of interest at that time, there were not many epidemiological studies available.

Now, with respect to the UCSF study, first off, we don't need to guess. We don't need to speculate. There is no material change between the draft manuscript and the final paper. No material change whatsoever. No need to speculate. The data is there.

Now, counsel mentioned a weak correlation between water fluoride and urine-fluoride in that relatively small cohort. Correct, there was a weak correlation. There is a very plausible reason for that.

The fact of the matter is if you're leaving your home, say, in a non-fluoridated community and you're going to San Francisco for a day or two, you're drinking some fluoridated water during that day or two, that's going to

obscure, Your Honor, the relationship between your home water fluoride level and your urine-fluoride level.

But the key fact of that study, Your Honor, is when you look at the urine-fluoride range in the women who came from the fluoridated areas, it's squarely in the range that we see in Canada.

And as Dr. Grandjean explained, it is biologically impossible for the average urinary fluoride levels among women who actually drink fluoridated water to be below the BMDL. The BMDL is about .15. And if you're drinking fluoridated water, we already well know that the concentrations in urine are going to be right around, you know, given or take, the level in the water.

THE COURT: Is there any evidence about the level of fluoridation in San Francisco water compared to the NHANES table?

MR. CONNETT: Yes. The level in San Francisco is .7 parts per million.

Now, NHANES is an important point, Your Honor. So I want to make one thing emphatically clear, because the record in this case is uncontested and undisputed on this point.

The Centers for Disease Control has never, ever, ever issued or published any urinary fluoride data for any population for any age group. EPA knows that. We deposed the CDC in this case. They said they have never published any

urinary fluoride data.

What they did have, Your Honor, is in 2015 and '16 the CDC collected some urinary fluoride data, but they have not yet released it. And in the population that they collected the urinary fluoride data was, it was for children 3 to 19.

There is -- counsel -- EPA right now today could not say truthfully that the CDC has ever collected urinary fluoride data for pregnant women in this country.

THE COURT: What about my question about the level of -- I take it your position is that the .7 parts per million is common throughout the country?

MR. CONNETT: Absolutely, Your Honor. There are still -- interestingly, there are still some areas where they haven't yet adjusted downwards to meet the recommendation from 2015, where the CDC and others recommended we lower the levels from upwards of 1.2 ppm down to .7. Some communities are lagging behind on that. But absolutely, the target concentration is .7.

I would also note that the CDC allows water municipalities to have a range of up to about 1 part per million because they recognize it's somewhat difficult to keep it precisely at .7 on any given day.

Now, with respect to -- counsel mentioned that one of the risk evaluations that EPA did, I think it was for methylene chloride, found causation. I think she mentioned death and

acute toxicity. I strongly suspect, and I believe the record will show, that's causation at a very high level.

I think Your Honor's question was about causation under the conditions of use. I don't believe under the conditions of use in that risk evaluation human beings were dying. So I think that we need to distinguish what we're referring to there with the causation.

And, Your Honor, that's all the comments I have. I appreciate your opportunity to provide a rebuttal.

THE COURT: All right, thank you.

All right. Here is what -- I want to talk to the parties about -- and I appreciate your closings and your presentations.

I had previously determined that the evidence in this case, given *de novo* review, given the comments in the legislative history, were not confined to the administrative record. And, obviously, we've gone well beyond the administrative record because so much has changed since that record, that petition was filed with the EPA. And I think that timeline that Ms. Carfora shows that.

There have been two significant series of studies, prospective cohort studies, which everybody agrees is the best methodology. Everybody agrees that these were rigorous studies. I think everybody agrees that these studies would be part of the best available scientific evidence.

You also have the UCSF study, which provides one -- and I

know it's disputed, but one potential link or brick in the generalizability of the Canadian and the Mexico studies. These are significant developments.

I had also ruled initially that I wasn't going to extend the trial date and allow discovery into the NTP then draft monograph. There was a motion initially, I think, by the government to -- to allow -- to not allow its inclusion? I can't remember which way it went to. To exclude it; right?

MS. CARFORA: No. To include it, but to have expert discovery on its interpretation.

THE COURT: Right. But there was later, I think, a Motion in Limine after that.

In any event, the parties came to an agreement not to introduce it, for whatever reason. So it's fine. So it hasn't come in.

But the Court is aware that this is a significant study. It's coming from the NTP. And they are using methodology, it appears -- and I haven't seen the peer review. I haven't seen the National Academy of Sciences peer-review comments. But it is obviously an important piece of evidence, whether you agree with it or not, how reliable ultimately it is. And that seems to be forthcoming perhaps any day.

But the main consideration I have is I have sat here now for two weeks listening to the expert testimony, reading the documents. And it occurs to me, more than ever now having

actually experienced and heard the evidence, that what is before this Court is an entirely different body of evidence -- not entirely, but a substantially different body of evidence that was presented to the EPA.

It also occurs to me that -- pursuant to the colloquy I had with Ms. Carfora, that the EPA appears to have applied a standard of causation which, from my read of TSCA, is not accurate. Is not a proper -- is not a proper application. It's not the proper standard.

I understand that it's part of the spectrum and it informs the consideration, but the -- but it appears that the EPA operated on a standard of causation and not allowing for association, perhaps even a strong association or a sufficiently strong association, to find an unreasonable risk that might be short of an actual finding of more likely than not causation.

All this counsels to me to pause for a moment and say, you know, why are we here? Doesn't it make sense to have the agency take a second look? Take a look now that the evidence has been produced by both sides, and maybe it can be refined. And it's going to be informed, hopefully, soon by the NTP. There may be some other things. There is the pooled study that Dr. Lanphear is hoping to -- I don't know how long that's going to be. And you've got the Spain study that is not in published form, not been peer reviewed yet. But who knows? I don't know

how long that takes.

But the point is, what was presented to the EPA was a very, very different record than what I have now. And although the Section 21 of TSCA confers upon the Court the power to act in the face of inaction by the EPA if the proper findings are made, as you can see, this is an enormous task. It is a task that this Court may well have to undertake, if necessary.

But I have to say, it seems to me, that even if there is no formal doctrine of administrative exhaustion, and I don't see anything in the TSCA that requires it, other than having petition and going through the process, it -- I don't know if it contemplated a situation where the record before the Court under a Section 21 petition is very, very different and has evolved substantially differently than what was presented.

And so my question to the parties is whether it makes sense for you to discuss possibilities of either an amended petition and reconsideration by the EPA or, if necessary, start a new petition, since it's a fairly rapid process, and to hold my decision and my adjudication of this in abeyance and give the agency a chance to relook. And, hopefully, relook at it under the proper standard of review.

I know I'm springing this on you, so I don't expect you to -- and I know you're going to have some initial reactions. Mr. Connett is distrustful of the EPA, et cetera. So I can predict that.

But I ask you to -- you can comment now, but I'd like you to think about that, and whether there is a way to allow the agency, and really at the urging of the Court, to take a second look.

Because there is serious evidence here. There is no doubt that these two studies from Canada and Mexico raise serious questions. And the witness -- Dr. Donohue, I guess; right? I know it's only one line out of a deposition, but her comment about: Well, it may be an appropriate time to reassess and revive, to relook at this whole question.

And I -- you know, and this is coming from somebody who knows her stuff.

MS. CARFORA: Your Honor, if I may?

THE COURT: Yeah.

MS. CARFORA: I don't want to harp on, you know, this difference in statutes. But Joyce Donohue works in the Office of Water, and that is a different program under a different statute. And that's -- you know --

THE COURT: All right. I'm not relying just on Joyce Donohue.

MS. CARFORA: I understand. I understand.

THE COURT: She expressed a sentiment that it seems so obvious.

MS. CARFORA: I understand. And you should know that the Safe Drinking Water Act requires EPA to review their

standards every six years.

So I believe -- I'm sure my colleagues will correct me if I'm wrong, but I believe the last one was 2016. So the Office of Water under EPA, under the Safe Drinking Water Act, is required to review their statutory standards in 2022. So that's -- that's the Safe Drinking Water Act.

But I -- I want -- I anticipated this question, Your Honor. And it's something that I have been talking to my client about, not just over the past couple of days. It's something that actually Mr. Connett and I have been discussing since January, to find out if there was a place to go here.

And I just want to express to the Court, I very much appreciate, you know, the issue with fluoride that we're dealing with here.

But above and beyond that, the agency has other interests here. Because amended TSCA is a brand new statute. This is a case of first impression. And there's a lot of implications in terms of implementing the statute, quite frankly. So above and beyond fluoride, there's a lot -- there's many more considerations that the agency has to take here. And so that's a concern.

And the other issue is that in our conversations with Mr. Connett beginning probably early January, and then also very early on, the problem is that we have not been able to identify a statutory mechanism that would suggest the approach

the Court is suggesting. In other words --

THE COURT: Well, you mean a reconsideration or whatever? There is no such thing as a petition for rehearing before the agency?

MS. CARFORA: No. Not within -- you know, if the agency denies the petition, there is 90 days to file and get judicial review. So there is no -- you know, there is no mechanism in the statute for that at this time.

THE COURT: Well, there is always -- if there is no other such mechanism, you can always file a new petition; right? There is nothing prohibiting that. You can file a new petition.

I don't know what the doctrines of res judicata and collateral estoppel are in the administrative field, but this would be based on wholly different new evidence. So I -- worse comes to worse, if people can't find a way to do it more efficiently, I mean, that's an alternative, too.

And, frankly, we do have the issue of standing here. I mean, the last thing I want to do is go through a detailed analysis into the substance of this. And if I find standing and get to the merits of this one way or the other and then, you know, have the work completely thrown out because of standing. Seems to me that's another reason to consider a petition.

Frankly, I don't know. You know, seems to me that it's

obvious who would have standing, where there wouldn't be a question.

And so at the end, it could save a lot of heartache and a lot of headache if we do kind of a reboot. It's not just a reboot for that purpose. It's because there has been evolving scientific evidence in the last three years now -- four years, almost four years.

MR. CONNETT: Your Honor, we certainly appreciate the Court's guidance and input on this. And we certainly want to give this, you know, due consideration. And I'm certainly happy to speak with counsel and see where we may have potential agreements.

I would -- as you picked up on, I -- you know, plaintiffs have been frustrated over the years with EPA's -- really, Your Honor, it has dragged it's feet for a long, long time. The NRC concluded in 2006 that the current safety standard is outdated and unsafe, and EPA still has not done anything to lower that standard.

So we are in a situation where the EPA has sort of made a political decision not to do anything. And that is precisely why plaintiff brought this petition in the first place.

THE COURT: Well, I understand your feelings about that. I'm not going to say one way or the other whether that has validity or not.

But what's different is not only the state of the

scientific evidence, but the posture of this case. We have a live case. I have a Section 21 case right now. And if I, as a matter of case management say, all right, I'm going to take this under submission for now, but I want you all to do -- you know, go back to the administrative process. That doesn't mean this case goes away. I still have this case. I could rule on this case. And I'm sure the EPA would be aware of that.

As well as the plaintiff would be aware that if I rule on this case, I might not come out in your favor. I mean, you all don't know which way I'm going to come out at this point.

So just as a matter of -- of procedural context, we would still be in litigation. I'm not dismissing this case. I would probably just take it under submission or put a pause on it. A stay maybe and say: Go back to the EPA through one mechanism or another.

Now, if that doesn't resolve it, I guess you're back here again. Whether it's on a new petition or we just revive this. You know, there's all sorts of procedural things that we could do.

But my main point is that, really, I would hope that the agency would take a serious look, apply the proper standard, and look at this new evidence. And there is going to be more stuff coming out in the next couple months. I don't know which way it's going to go.

But I do think that that makes sense, given the

seriousness and the consequential impact of whatever we do, whatever the EPA does.

I understand it's just a threshold showing and it would kick in rule-making if plaintiffs were to prevail, so it doesn't end the inquiry. But it's still a significant issue on all sides, you know, for reasons stated by both.

I'm aware the EPA -- there is a lot of pressure. The prioritization of the chemicals and everything else. That's why Section 21 allowed for some breathing space when you get into rule-making and all that.

But, you know, it's not like we're starting fresh here. There are people, it's not like they don't know anything about this issue. It's not like coming out of the blue. The record in this case is now public. The studies, the deposition -- you know, all the stuff. The body of evidence is there. It's growing, but, I mean, it's not like we're starting from nowhere.

So that's why it occurred to me.

MR. NIDEL: Your Honor, this is Chris Nidel. I just had a question related to your recommendation.

THE COURT: Yeah.

MR. NIDEL: Would there be -- would you envision some limited discovery on any new additional studies or available information that comes out?

THE COURT: You mean, if it came back to court?

MR. NIDEL: So, for example, if NTP came out with their assessment, their final assessment, and, you know, for -- for some of the reasons that have been stated, plaintiffs were skeptical of some of those -- some of the bases or some of those conclusions, or just wanted to get discovery from NTP on how that evaluation was done and what was considered, would that be a tool that might be available to us?

THE COURT: All right. What's the government's response to that?

MS. CARFORA: Your Honor, I'm not insensitive to any of this. So, you know, the problem is that they are very -- there are very specific statutory limitations on the authority that EPA has here, and there are very specific limitations on the authority that the Court has here.

And regardless of whether we have more -- we have more discovery and we have more trial, at the end of the day, unless plaintiffs can produce to this Court a risk evaluation that meets the scientific standards and the rigors of that required under TSCA, the agency does not have the resources or the ability to conduct a risk evaluation for fluoride outside of the prioritization process. And that's -- there is some very specific legal limitations that we think drive that.

THE COURT: Well, are you saying that if somebody -- let's say somebody else filed a petition. Are you saying that that is going to be denied for lack of resources? That the EPA

could not comply with the statute and render a -- I mean, there would be inaction, is what you're telling me, and the 90 days would run?

MS. CARFORA: No. I'm not suggesting that at all. And I want to try to be, you know, very clear.

EPA only has 90 days to review a petition under the statute. That's the legal limitation. They have 90 days.

The position we've taken in this litigation is that -- and this is consistent with the guidance that we've put out, that EPA has put out to the public, which is we welcome the public's health -- help, in helping us, in helping EPA evaluate these chemicals, but there is specific guidance in that interested persons should follow that guidance and produce to EPA an evaluation that meets the same rigor and statutory standards required by Congress -- required by the statute. And that that would be necessary. That would be the level of evidence necessary for EPA to be able to reach a determination of unreasonable risk within the 90 days that it has to review a petition.

In other words, the risk evaluation rule and Section 6B gives EPA up to three and a half years to do an evaluation. There is no way EPA could do a risk evaluation within the 90 days it would take for -- that they have to review a petition.

And so the position of the agency has been, and continues to be, give us the information we need that meets the statutory

standards so that we can make a risk determination within the 90 days provided under Section 21.

And so we would never in any case pre-determine any decision on a petition or any other decision EPA might make. They don't make any pre-determinations. They have to be able to -- within the statutory limitations, be able to make their finding based on the information that's submitted in the petition.

THE COURT: So you're saying that if the petition -- let's say a new petition or amended petition, whatever you want to call it, is filed and in the view of the EPA procedurally it doesn't meet the rigors of a risk evaluation with all the elements. I guess you're suggesting systematic review being part of that? I assume that's what you're saying?

MS. CARFORA: So I'm trying to be very -- trying to be very clear.

The position of EPA is that the petition has to meet the best available science and weight of the scientific evidence requirements of the statute. EPA believes and has codified a definition for weight of the scientific evidence.

And so -- I'm not saying that petition has to do that. The EPA might require that.

What Dr. Henry actually testified to the other day is that all the right pieces would have to be in all the right places for EPA to be able to have the information it needed to make a

decision within 90 days. And that doesn't mean that it has to follow exactly EPA's procedure, but it means that all the right information has to be in all the right places.

THE COURT: Well, all right. That is something that you have the advantage of being able to meet-and-confer in advance knowing the record as it is. You can have a meet-and-confer to see if any new petition or amended petition, or whatever it's called, is sufficient to trigger a substantive -- a meaningful substantive review.

True, it has to be done within 90 days. I guess there is no way to -- there is no statutory way to extend that; is that correct?

MS. CARFORA: That's correct.

THE COURT: All right.

MS. CARFORA: That's one of the limitation that we have.

THE COURT: But rather than being hit by a petition out of the blue, you all are in this case. You all are communicating. You certainly can have some communication about what it takes to trigger a meaningful substantive review, because I think that's what we're all after. Not just some procedural ruling by the EPA saying: Well, we don't really have time to deal with this because you didn't do it in this form and, therefore, we are going to deny that. That's not going to be very helpful. That's not what I'm hoping for. I'm

hoping for a substantive review.

And I think, you know, you can meet-and-confer and see if you can come up with something that -- I won't call it pre-clearance, but something sort of pre-cleared by the EPA so you know it's not just going to be kicked out on procedural grounds. It will be whatever the form is sufficient to trigger substantive review.

I mean, it seems to me that, you know, the better minds in the legal field, including yours, all of you, should be able to figure that out.

MR. CONNETT: Your Honor, on behalf of plaintiffs, I am happy to speak with EPA to discuss some of these possibilities.

I would note for the Court a concern that I have, just thinking about this now. And that is that as you may imagine, this has been a pretty -- for citizen groups has been, I think fair to say, a massive undertaking. We have spent now about four years.

And the concern I have is if we -- you know, the idea of starting a new petition, the resources and time involved with that is something that may be prohibitive for the citizen groups.

So, you know, we certainly believe we have presented sufficient evidence to demonstrate a risk under the proper standard under Section 6.

So that is our -- that's my main concern, Your Honor, as I think through this out loud.

The -- so I just want to just put that out there for the Court. That's my main concern, thinking about this.

Another thing, thinking out loud here, is to the extent that this was to be stayed in some degree, in some fashion, we would certainly want to see EPA do something now to help begin trying to protect the public. For example, starting to warn people, pregnant mothers, about the risk that we now see here in the science.

Because EPA has done absolutely nothing. And, you know, it's -- you know, as we saw in the Bradford Hill statement, Your Honor, you know, we can't ignore the evidence that we have in front of us. And for so long the EPA has done nothing. They've done nothing to protect the public from the risks.

And we could do a risk evaluation that lasts another four years. And in the meantime, you have hundreds of millions of people who are experiencing this risk.

And the statute, the Toxic Substances Control Act, was designed -- was designed for the precise purpose of not having to expose people for risks. Just, you know, so you wait for the final proof, to the final causation. Congress amended TSCA --

THE COURT: It does require, before a regulatory action is mandated, a finding of unreasonable risk, even if not

causation.

And so what you're asking for is almost -- I don't know if you're asking for the Court to order something or you're saying that's something that you'd like the EPA to do.

MR. CONNETT: Yes, Your Honor. It's what gives me apprehension about any process that would conceivably extend this by potentially years, is that we are back to the situation where we have a clearly identifiable --

THE COURT: I don't know about years. I didn't say this case was going away. This case has been tried. I have the record and if I have to, I will rule on it.

But I'm thinking months, not years. Because for you to re-craft -- and I understand the resource issue. But, frankly, you've devoted so much -- so many resources into this case, and you've got a lot there. You may have to do a little -- may have to do some work. I don't know how much more. But if you can get it in a form that is sufficient to trigger substantive review, you know that once you do file it, there is a 90-day clock on it and, you know, then we'll see where we're at.

So however long it takes you to re-craft -- meet-and-confer and then re-craft something. You file it. It's a matter of months, not years. And if it comes back here, in whatever form it comes back, we've already tried this case, you know, and -- so you wouldn't be starting from scratch. It's not like starting all over again, I wouldn't think.

Now, you know, if you file a new action based on a new petition, we have to figure out whether we consolidate. I'm not going to forecast every procedural nuance. But I don't anticipate that I will be sitting on this for years if there is no resolution.

MR. CONNETT: Understood, Your Honor. I'd like --

THE COURT: Go ahead.

MR. CONNETT: I was going to ask for any guidance from the Court in terms of -- I'm happy to, like, begin a meet-and-confer process immediately with Ms. Carfora and DOJ counsel to just start discussing this; right?

Any guidance from the Court as to whether -- you know, in terms of meeting back up with the Court to discuss this further, kind of that sort of time frame?

THE COURT: Yeah. My plan would to be ask you to meet-and-confer, to see if you can figure out a procedural, you know, mechanism and a process that would effectuate what I'm talking about.

And then I'd like to have a further status conference to see where we're at. I don't know how many -- you know, sort of I leave it to you whether that's three weeks out, you know, two weeks? Four weeks? Five weeks? You know, whatever you think. Six weeks? Two months? You know...

MR. CONNETT: For plaintiff's position, it would be the earlier. So we -- would, if it's two weeks or three weeks,

that would be our preference.

MS. CARFORA: We request at least 30 days, Your Honor.

THE COURT: All right. Well, I think that's a fair request, because it's a big ask. I understand that. And there are limitations on both sides. There's resource issues, frankly, on both sides. You've got EPA with all its priorities, statutory priorities, and everything that's going on. You've got citizen plaintiffs with limited resources, and so I understand that.

And, yet, I'm trying to think of what the most coherent way to approach this overall problem is, and it just seems to me this -- that makes sense.

So why don't I -- Angie, why don't we set a come-back status conference in 30 days? And then if I can ask you, just send me a joint statement, a brief update as to whether you are, you know, five days before.

MR. CONNETT: Will do, Your Honor.

THE COURT: Okay.

MR. CONNETT: Your Honor, in terms of post trial briefing with respect to findings of fact or briefing on standing, what is your -- what is the Court's preference on that?

THE COURT: Well, I would like to have that. I'm hesitant to impose on counsel, you know, to do two things at

once. But since it is fresh in your minds, fresh in our minds and, you know, there is a likelihood I'm going to have to rule one way or the other. I mean, that is a possibility.

And what I said initially about having findings of fact that's keyed to some document cites, some exhibits, that's very helpful. Otherwise, this is -- even though it's only been a two-week trial, there is a lot here. So I would like that.

You know, normally I would ask a for that in a couple weeks, but I'm not going to do that. I'll give you some more time. I would say within the same 30-day period, if you could do that?

MS. CARFORA: Your Honor, we would actually request 60 days for that, and here is why.

We're going to meet-and-confer and have this process. We're happy to do that. But the agency does have a number of risk evaluations that are being finalized right now and being published, and the program is very taxed right now.

And, you know, I just -- I think 30 days to do both post trial briefing and have the type of conversations we need to have within the agency and with DOJ around some potential alternatives here is just going to take a little bit more time for us.

And so if -- if we want to confer in 30 days and have 60 days for post trial briefing, or the other way around, but I -- I don't think we can do both in 30 days.

MR. CONNETT: Could we ask for 45 days, Your Honor?

THE COURT: Let me tell you, I have one very practical limitation, and that is my staff that's been working with me on this case, there is -- as you know, there's always a turnover. And the last thing I want is to get findings of fact and have somebody new who has never heard this case. I don't think it would be to your benefit or to mine.

So, if anything, that's going to be a priority. I would rather give you more time to talk about the resolution. I do need those findings of fact and conclusions of law. I can give you --

MR. CONNETT: From plaintiff's perspective, we can get those to you next -- we can get them as soon as you want them. Obviously, at the same time as EPA does, but we have no concern about getting them to you whenever you want them.

THE COURT: I will need them by July 27th. That gives you the weekend, but I will need those by the 27th.

MS. CARFORA: And can you -- I'm sorry. It's not post trial briefing. It's just an update on the --

THE COURT: Yeah, I don't need -- I've heard your argument. I don't think I need any more sort of argumentation. Actually, if you could take whatever -- and you don't have to change your actual findings of fact because you've already submitted those, but update those to what the evidence conformed to. Really, the citation that's helpful.

MR. CONNETT: And, Your Honor, on the briefing. Plaintiffs would like to, with the Court's permission, submit a brief on standing, because we do believe that there is additional case law that we haven't yet addressed, and we believe we can provide the Court a very helpful analysis of the evidence.

THE COURT: That is the one issue that I was going to ask. I started to ask Ms. Carfora some of those questions.

So I would like to give the parties a chance to re-brief the standing issue, now that we have the record and. So that -- I don't need, you know, 50 pages. I need maybe 10 to 15 pages at most on the standing question. Because you've already briefed that to a certain extent. I will re-look at that.

But, yes, if you could submit briefing on standing. And you can do cross briefs on that. I don't need, you know, sets of three briefs. You can cross brief that, let's say, in 14 days? That's a legal question; right? So it shouldn't be that hard. Largely a legal question.

MR. CONNETT: And with respect to systematic review, would Your Honor want any additional briefing on that?

THE COURT: I don't need any more briefing on that.

MS. CARFORA: Your Honor, the standing brief, 14 days from today?

THE COURT: Yeah.

MR. CONNETT: And the findings of fact, Your Honor, did you say July 27th?

THE COURT: Yeah.

MS. CARFORA: I don't think we actually set a date for the status conference.

THE COURT: Angie was going to give me a status conference date.

Do you want it more than 30 days, since you'll have to be working on this. Like, 45 days?

MS. CARFORA: Yes. That would be great. Thank you.

THE COURT: Angie, 45 days out.

THE CLERK: Your Honor, July 30th.

MS. CARFORA: Your Honor, that's not very --

THE COURT: Let's go a little longer than that. How about the week after that?

MR. CONNETT: Oh --

THE CLERK: August 6th at 10:30.

THE COURT: Okay. All right.

MS. CARFORA: Can I --

THE COURT: Yes.

MS. CARFORA: I assume, Your Honor, because we're just so good at it at this point, we can do that either via teleconference or Zoom?

THE COURT: Yeah. Yeah. We're not -- highly unlikely we'll have any live civil hearings for awhile. So

we'll do this by Zoom again.

MS. CARFORA: Great.

THE COURT: We'll send out a notice for that.

MR. CONNETT: I might be on vacation, Your Honor, so I might be in a little bit more informal place, but that works.

THE COURT: I understand. Well, if you're going to do that, I'll take off my robe and my tie because it's been killing me.

All right. So let's do that. And at this point the record for the trial is closed. It's completed. And subject to receiving your proposed findings of fact and conclusions of law, I will await to take it under submission. But so that's the state of the record at this point.

So let me thank the parties. I know both of you have worked very hard, and this is a complicated issue. And I have found that the presentations have been informative and very helpful. So thank you.

MR. CONNETT: Thank you, Your Honor.

MS. CARFORA: Thank you.

And we thank -- can we thank Angie for how wonderful she was figuring out the Zoom so quickly and making everything run so incredibly smoothly.

THE COURT: I will join in that thanks. I see you're smiling.

THE CLERK: You're very welcome.

THE COURT: She's done a terrific job. Especially this is our first time out doing this and, I think it worked well.

I also want to thank our IT staff. Buz, who you met a couple times, really was instrumental in making sure this worked. But I think this shows that the process, not ideal, but, you know, on these -- in these difficult times at least we can still do court business. So thank you for your -- your flexibility as well. I appreciate it.

MS. CARFORA: Thank you.

MR. CONNETT: Thank you, Your Honor.

THE COURT: Thank you.

THE CLERK: Court is adjourned.

(Proceedings adjourned.)

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CERTIFICATE OF OFFICIAL REPORTER

I certify that the foregoing is a correct transcript from the record of proceedings in the above-entitled matter.

Debra L. Pas, CSR 11916, CRR, RMR, RPR

Wednesday, June 17, 2020